Telecon, November 11, 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: 11-November-2011 12:00 PM Initiated by FDA? Yes
Telephone Number: -----(b)(4)-----
Communication Categorie(s):
1. Clinical Indication 2. Inspection Related 3. Donor Eligibility

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Telecon Summary:
1. Clinical Indication 2. Inspection Related 3. Donor Eligibility

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Trans-BLA Group: No
Related STNs: None
Related PMCs: None

Telecon Body:
Clinical indication

Following introductions, the clinical team at FDA recommended that the Sponsor withdraw their indication listed in the current 356 and submit a new 356 with modified language that will be provided to the Sponsor via email. The Sponsor agreed.

DMPQ
DMPQ stated that they would like to go over batch records with the sponsor, they also added that it is important to have pertinent information on master batch records, since this is the information often looked for during subsequent inspections. DMPQ started with D3.201, for this batch record it was stated that more detail and specificity was needed in the following area:

Collection sites – sponsor will have to add details such as minimum and maximum temperature at arrival, date and time of collection, processing room locations and numbers.

Cord Blood Freeze Time– Specify how age is defined at freeze time from collection to cryopreserve, time taken for processing ------(b)(4)-----.

Acceptance criteria – define acceptance criteria was met

Cryopreservation – what are the parameters used, rate of cooling defined as x°/min and ensure all parameters have been met as specified.

Freeze solution temperature – define what freeze solution temperature is, ensure each step is recorded, indicated criteria met or not.

Materials and reagent sections – Specify catalog and log number of reagents.

DMPQ stated that batch records should also contain all calculations, though some instances can be cross referenced. DMPQ advised the sponsor to add headings to compartmentalize sections clearly organize their documents, label correctly. DMPQ also recommended the sponsor to add 2 boxes listing --------(b)(4)--------- processing so one could be checked based on the process used.

Donor Eligibility
FDA informed the sponsor that the Medical Director Review form (Form D3.101.4) only refers to the acceptability of the maternal questionnaire. Sponsor explained that a 2 page processing record was originally included with D3.101.4, but was deemed insufficient and need for a batch record that could be checked off was created. Since following 2 documents was confusing, the sponsor added additional information to the master batch record. Donor eligibility information transferred to the master batch record includes:
Review of the maternal questionnaire and maternal assessment form.
Sponsor was informed that in addition to the maternal questionnaire, the review of donor testing, medical and physical examination records should also be reviewed and signed off by the medical director. Sponsor was also informed that the final DE

determination and reason for ineligibility if applicable should be documented and signed off by the medical director