

Telecon, January 10, 2012 - 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-January-2012 12:00 PM

Initiated by FDA? Yes

Telephone Number: -----(b)(4)-----

Communication Category(ies):

Outstanding Issues

Author: RAMANI SISTA

Telecon Summary:

Flow Cytometry

FDA PARTICIPANTS:

Yong Fan

Fatima Abbasi

NON-FDA PARTICIPANTS:

Brian Freed

Sabine Stockinger

Linda Tapia

Michael Aubrey

Deborah Schubert (Supervisor, Flow Lab)

Sharon Miller

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body

The following issues were discussed with the sponsor:

1. Although in attachment 29, page 6 it states, "Ensure that the -----
----- (b)(4) -----, the sponsor provides no SOP
for this procedure. Please provide SOP for ----- (b)(4) -----
-----.

Sponsor explained that they use -----(b)(4)-----
----- . They will scan and email the SOP for these procedures.

2. Please provide -----(b)(4)----- instruments. This data is saved in the -----(b)(4)-----.

Sponsor explained that they do keep records of -----(b)(4)----- . They have pulled the data for the month of December. On our request they agree to pull the data for three months for (b)(4) instruments and scan and email to us.

3. Please clarify which kit is being used? Your application makes reference to two kits: -----(b)(4)-----
--.

Sponsor verified that they are using FDA approved ---(b)(4)---, which is manufactured in (b)(4). They said --(b)(4)-- kit is not longer available.

4. Please explain what kind of accreditation and proficiency testing is being done to ensure the quality of the CD34 testing. Is the -----(b)(4)----- lab CLIA certified? Is it licensed by the Colorado State Department of Health to perform cellular immunology testing? Are proficiency test results on file?

The sponsored explained that both labs, Clinimmune and University Hospital laboratory are CLIA and CAP accredited. Proficiency testing is done as part of CAP accreditation.

5. Are the ----(b)(4)---- operators training records available? Is competency of operators assessed annually?

Sponsor has the training records of all the ----(b)(4)---- operators on file and they do participate in annual proficiency testing through CAP. Sponsor will send the records.

6. Regarding dilution for -----(b)(4)-----
-----?

7. For your validation studies could you clarify how you compare performance between different operators?

Sponsor has provided the data on precision, and validation for (b)(4) instruments. This is done by all operators. Sponsor suggested since each operator can be identified by their ID or name, data can be sorted based on operator. Sponsor will send this data.

Since operators participate in proficiency and competency testing and these results are on file, this should address operator differences.

8. Please confirm that ---(b)(4)--- is no longer being used for validation of cord blood samples. Sponsor verified that only ---(b)(4)--- instruments are being used in lab and ---(b)(4)--- is no longer present in the lab.

Sponsor will send all the related documents and SOP, first by email and then as an amendment to the submission.