RECORD OF TELEPHONE CONVERSATION

Submission Type: BLA Submission ID: 125585/0 Office: OCTGT

Product:
Hematopoietic Progenitor Cells, Cord (HPC-C)

Applicant:
Puget Sound

Telecon Date/Time: 22-May-2015 12:00 PM Initiated by FDA? Yes

Telephone Number: (b) (4)

Communication Categorie(s):
Sterility Test Validation Discussion

Author: Joy Ghosh

Telecon Summary:
Sterility Test Validation discussion
1. Package inserts for (b) (4) .
2. 1.6.4 Reply to FDA questions of 07-18-14.pdf
3. 3.2.S.4.3.2.1 (b) (4) Validation Report.pdf
4. 3.2.S.4.3.2.1A (b) (4) Addendum.pdf
5. Letter to Joydeep Ghosh, Ph.D. 2015 04 21.pdf

FDA PARTICIPANTS:
Ramani Sista
Joydeep Ghosh
Brian Niland
Kim Benton

NON-FDA PARTICIPANTS:
Rebecca Haley
Carol Hayler
Andrea Bradford

Telecon Body

FDA pointed out that the new validation data suggest that the applicant has done the validation using just (b) (4) the (b) (4) instead of (b) (4) for both the aerobic and the anaerobic sample. The applicant confirmed that (b) (4) was indeed used for all validation studies.

FDA stated that the applicant needs to test at least (b) (4) per media for the product release test and as they have validated the bacteriostasis/fungistasis using just (b) (4) sample they would have to either

1. Test (b) (4) each of aerobic and anaerobic media for each cord blood sample (to test a total of (b) (4) sample per media in order to obtain the same level of sensitivity as other banks have done), or

2. If they would like to use just (b) (4) each of the aerobic and anaerobic media per cord blood lot, validate everything using (b) (4) for both the aerobic and anaerobic microorganisms and submit the data for review.

The applicant stated that they will revalidate their method using (b) (4) for both the aerobic and the anaerobic microorganisms and submit the data for review.

The applicant said that as they already have the data for (b) (4) from a previous study they would not repeat that experiment. FDA requested the applicant to include a clarification regarding the inhibition data for (b) (4) in their next amendment that would confirm that

1. No changes were made to their (b) (4) equipment hardware or software and

2. The respective assays also used the (b) (4) .

The applicant agreed to provide that clarification.