

Re-validating Telecon, Ducord

RE: Teleconference Re-validating the ---(b)(4)--- system for testing product sterility

Time: 3:00pm

Attendees can use the following number for the call:

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

Passcode: ---(b)(4)---

Duke University (Sponsor) is requesting follow-up regarding Carolinas Cord Blood Bank's plans for re-validating the ---(b)(4)--- system for testing product sterility. During the February 3, 2012 teleconference, FDA indicated that the sponsor would have to repeat the Phase 2 study that was submitted in the original application with the appropriate --(b)(4)--- sample (----- (b)(4) -----). But, prior to completing this study, FDA suggested that sponsor perform a pilot study to help assess the distribution of the organisms in the post-processed components and to see if ---(b)(4)--- might be inhibiting microorganism growth.

Discussion: Basically, sponsor experiment plan appears to be ready to proceed.

1. The sponsor clarified that they will be checking the (b)(4) from both the sources of microorganisms (----- (b)(4) -----).
2. For plating we recommended that they do triplicate instead of duplicate.
Sponsor agreed.
3. The sponsor clarified that for this distribution verification study the actual inoculum per unit of unprocessed cord blood will be ----- (b)(4) ----- (We would prefer that use less than (b)(4) per cord blood unit but there is no regulation to enforce that limit. (b)(4) also used ----- (b)(4) ----- inoculum per unprocessed CBU to check the post-processing distribution of microorganism in each fraction)
4. The sponsor clarified that they will use ---(b)(4)--- inoculum per bottle when they do the repeat of their Phase 2.

The sponsor will begin planning for this validation process during the week of Monday, March 26th.

Attendees:

Joydeep Ghosh

Mark Davidson

Duke University:

Bruce Burnett, PhD- Director, Regulatory Affairs,

Amanda Parrish, PhD- Regulatory Affairs

Page Last Updated: 11/02/2012

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