From:	Jarvis, Candace
To:	Evans, Jill A.
Cc:	Jarvis, Candace; Heidaran, Mohammad; Dollins, Eric; Haudenschild, Changting; Borigini, Mark
Subject:	Request for information and Request for a teleconference/ BLA 125432
Date:	Thursday, October 18, 2012 3:24:34 PM
Attachments:	125432_20121018_IR.pdf
Importance:	High

Good afternoon Jill,

1) The agency request that you submit the following information to us regarding your post-marketing plan. This would be considered as a written agreement for post marketing:

"We agree that if our HPC, Cord Blood BLA is approved, we will implement the following specific post marketing activities in addition to your existing SOP (Clinical Outcome Data, CCBB-Admin-014) and Risk Management Plan:

- Implement a safety outcomes monitoring and analysis plan. This plan will include a) maintenance of an observational database to include, for all HPC, Cord Blood units released, information experience reports, and c) safety outcomes analyses of interval and cumulative data that address early mortality, graft failure-related mortality, graft failure, time to neutrophil recovery, infusion-related events, and other adverse experiences. Reports will include a description of the population analyzed, results of the analyses, whether outcomes indicators were triggered and, if so, what actions were implemented as a result.

- Submit a 15 day "alert report" for each serious infusion reaction associated with administration of HPC, Cord Blood.

Please submit this information as an amendment to the BLA.

2) The agency is requesting teleconference to discuss the following:

a. SOP for linkage of DIN with maternal ID
b. SOP reflecting exclusion of mother's receiving antibiotics
c. Package label ISBT 128 compliance
d. Proprietary name request
e. Revalidation of emergency recovery
f. Flow Cytometry (specific questions in attachment)

Please choose from the following three dates that are feasible for your team:

Wednesday, October 24th 11-12PM EST
Wednesday, October 24th 1-2PM EST
Thursday, October 25th 12-1PM EST

Please provide a call in number for the call.

Thank you,

Candace N. Jarvis
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