

**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  
Regulatory Project Manager  
FDA/CBER/OCTGT  
1401 Rockville Pike HFM-705  
Rockville, MD 20852  
Phone: 301-827-5357  
Fax: 301-827-9796  
[candace.jarvis@fda.hhs.gov](mailto:candace.jarvis@fda.hhs.gov)*

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender immediately by e-mail or phone.