

**From:** [Jarvis, Candace](#)  
**To:** [Jarvis, Candace](#); [Williams-Gould, Juanita](#); [Deneke, Grace](#); [Hogue, Atm.S.](#); [Serabian, Mercedes](#); [Lin, Stan](#); [Zhen, Boguang \(CBER\)](#); [Cortez, Karoll](#); [Heidaran, Mohammad](#); [Wonnacott, Keith](#); [Nguyen, Loan](#); [Stockbridge, Lisa L](#); [Sheikh, Jalal](#); [Ghosh, Joydeep](#); [Borigini, Mark](#); [Haudenschild, Changting](#); [Irony, Ilan](#); [Bryan, Wilson](#); [Simek, Stephanie](#); [Benton, Kimberly](#); [Puri, Raj K. \(FDA/CBER\)](#); [Hall, Angela](#); [Michaelis, Marion](#); [Syn, Chiang](#); [Ortega, Lillian](#); [Holobaugh, Patricia](#); [Karandish, Safa](#); [Witten, Celia \(CBER\)](#); [Riggins, Patrick](#); [Tull, Lori](#); [Liu, Ke](#); [Dollins, Eric](#); [Abbasi, Fatima](#)  
**Cc:** [Stevens, Ted](#)  
**Subject:** RE: Filing Meeting/BLA 125432/Life South/ CJarvis  
**Date:** Friday, July 06, 2012 10:43:31 AM

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All ,

Please note the update in red.  
By discipline:

DMPQ~ No filing issues; information will be requested

Clinical~ No filing issues; information will be requested

Labeling~ No filing issues

Product (DHT)~ No filing issues; information will be requested

Product (CMC)~ No filing issues; information will be requested

BIMO~ No filing issues

Pharm/Tox~ No filing issues

Updated

Statistical~ No filing issues

Also please note that I will need your final filing deficiency comments by July 10th to be included in the Filing Letter due on or before July 17, 2012.

If there are any questions or concerns, please let me know.

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)*

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**From:** Jarvis, Candace

**Sent:** Tuesday, July 03, 2012 2:15 PM

**To:** Jarvis, Candace; Williams-Gould, Juanita; Deneke, Grace; Hoque, Atm S.; Serabian, Mercedes; Lin, Stan; Zhen, Boguang (CBER); Cortez, Karoll; Heidaran, Mohammad; Wonnacott, Keith; Nguyen, Loan; Stockbridge, Lisa L; Sheikh, Jalal; Ghosh, Joydeep; Borigini, Mark; Haudenschild, Changting; Irony, Ilan; Bryan, Wilson; Simek, Stephanie; Benton, Kimberly; Puri, Raj K. (FDA/CBER); Hall, Angela; Michaelis, Marion; Syin, Chiang; Ortega, Lillian; Holobaugh, Patricia; Karandish, Safa; Witten, Celia (CBER); Riggins, Patrick; Tull, Lori; Liu, Ke; Dollins, Eric; Abbasi, Fatima

**Cc:** Stevens, Ted

**Subject:** RE: Filing Meeting/BLA 125432/Life South/ CJarvis

**Importance:** High

All,

Please note the update below in red.

I ask that you all please use the filing checklists that was included in the 21 day planning meeting agenda for your respective disciplines so that they may be loaded to the EDR.

By discipline:

DMPQ~ No filing issues; information will be requested

Clinical~ No filing issues; information will be requested

Labeling~ No filing issues

Product (DHT)~ No filing issues; information will be requested

Updated

Product (CMC)~ No filing issues; information will be requested

BIMO~ No filing issues

Pharm/Tox~ No filing issues

We are still waiting for the Stats team.

Thank you,

*Candace N. Jarvis*

*Regulatory Project Manager*

*FDA/CBER/OCTGT*

*1401 Rockville Pike HFM-705*

*Rockville, MD 20852*

*Phone: 301-827-5357*

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**From:** Jarvis, Candace

**Sent:** Monday, July 02, 2012 1:12 PM

**To:** Jarvis, Candace; Williams-Gould, Juanita; Deneke, Grace; Hoque, Atm S.; Serabian, Mercedes; Lin, Stan; Zhen, Boguang (CBER); Cortez, Karoll; Heidaran, Mohammad; Vatsan, Ramjay; Wonnacott, Keith; Nguyen, Loan; Stockbridge, Lisa L; Sheikh, Jalal; Ghosh, Joydeep; Borigini, Mark; Haudenschild, Changting; Irony, Ilan; Bryan, Wilson; Simek, Stephanie; Benton, Kimberly; Puri, Raj K. (FDA/CBER); Hall, Angela; Michaelis, Marion; Syin, Chiang; Ortega, Lillian; Holobaugh, Patricia; Karandish, Safa; Witten, Celia (CBER); Riggins, Patrick; Tull, Lori; Liu, Ke; Dollins, Eric

**Cc:** Stevens, Ted; Dollins, Eric

**Subject:** RE: Filing Meeting/BLA 125432/Life South/ CJarvis

**Importance:** High

Good afternoon Team,

Hope all are well.

Just wanted to give an update as we held the filing meeting this afternoon. The meeting was brief. As a consensus for those that were in attendance, this submission is filable; however, there will be some comments that will need to be relayed to the sponsor in the filing letter. We are due to issue the filing letter on July 17th if not sooner. I will need to have your comments by COB on July 10th or sooner. For those who were unable to call into the meeting, please have your filing recommendation to me no later than Noon, Thursday, July 5, 2012. (Note: Wednesday is a holiday) Please indicate if you will have comments to relay to the sponsor.

By discipline:

DMPQ~ No filing issues; information will be requested

Clinical~ No filing issues; information will be requested

Labeling~ No filing issues

Product (DHT)~ No filing issues; information will be requested

Please let me know if you have any questions.

Thank you,

*Candace N. Jarvis*  
*Regulatory Project Manager*

*FDA/CBER/OCTGT  
1401 Rockville Pike HFM-705  
Rockville, MD 20852  
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**From:** Jarvis, Candace  
**Sent:** Tuesday, June 05, 2012 9:45 AM  
**To:** Jarvis, Candace; Williams-Gould, Juanita; Deneke, Grace; Hoque, Atm S.; Serabian, Mercedes; Lin, Stan; Zhen, Boguang (CBER); Cortez, Karoll; Heidaran, Mohammad; Vatsan, Ramjay; Wonnacott, Keith; Nguyen, Loan; Stockbridge, Lisa L; Sheikh, Jalal; Ghosh, Joydeep; Borigini, Mark; Haudenschild, Changting; Irony, Ilan; Bryan, Wilson; Simek, Stephanie; Benton, Kimberly; Puri, Raj K. (FDA/CBER); Hall, Angela; Michaelis, Marion; Syin, Chiang; Ortega, Lillian; Holobaugh, Patricia; Karandish, Safa; Witten, Celia (CBER); Riggins, Patrick; Tull, Lori; Liu, Ke  
**Cc:** Stevens, Ted; Dollins, Eric  
**Subject:** Filing Meeting/BLA 125432/Life South/ CJarvis  
**When:** Monday, July 02, 2012 12:00 PM-1:00 PM (GMT-05:00) Eastern Time (US & Canada).  
**Where:** CBER Conf. WOC-200S

*Good Morning Team!*

*This is the **Filing Meeting** for BLA 125432. An agenda will be provided prior to the meeting.*

***Sponsor:** Life South*

***Product:** HPC, Cord Blood*

***Proposed use:** Unrelated donor hematopoietic progenitor cell transplantation procedures in conjunction with an appropriate preparative regimen for hematopoietic and immunologic reconstitution in patients disorders affecting the hematopoietic system.*

*10 Month Clock Due Date: March 18, 2012 [subject to change]*

*Please use the following call in information:*

(b)(4)

Thanks,  
Candace