

**From:** [Jarvis, Candace](#)  
**To:** [Downey, Edward M. Sr.](#)  
**Cc:** [Evans, Jill A.](#); [Heidaran, Mohammad](#); [Dollins, Eric](#); [Ghosh, Joydeep](#); [Jarvis, Candace](#)  
**Subject:** BLA 125432/Life South/ Request for Information  
**Date:** Friday, March 01, 2013 11:45:26 AM  
**Importance:** High

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Hi Ed,

During our teleconference with you the other day, we forgot to follow-up with your team regarding whether or not you would retest a sample in case of a sterility test failure. If yes, please submit the details.

Also, we would also like to know if you were able to detect the (b)(4) in the presence of the by-product on day 14 of your third repeat validation ex we recommend that you start trying the other media (i.e., (b)(4)) for validating the growth of obligate anaerobes.

Please reply with an email and when the validation is complete, please also submit as an amendment to the BLA.

Thanks!

*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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