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To: [Evans, Jill A. \(JAEvans@lifesouth.org\)](#)  
Cc: [Heidaran, Mohammad](#); [Dollins, Eric](#); [Jarvis, Candace](#)  
Subject: BLA 125432/Life South: Draft Labeling  
Date: Monday, June 10, 2013 11:36:12 AM  
Attachments: [BLA 125432\\_20130531\\_6\\_10\\_2013.docx](#)

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Good morning Jill,

Please find attached the Final FDA draft for the Package Insert. Please review, accept the track changes and remove bubbles for the items you feel are acceptable and understand. Please send the revised version back to us by tomorrow morning at 10 am to ensure a timely review.

With regard to the package labeling, please change Hetastarch to Hydroxyethylstarch with a capital H and should be placed on a separate line like Hetastarch was before. We will need this too by 10 am tomorrow morning.

We further request that you provide a revised container label by removing the wording in the middle stating "REMOVE THIS LABEL BEFORE PLACING ON BAG". We will need this too by 10 am tomorrow morning.

Please let me know if you have any questions.

Regards,

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