

**From:** Wood, Lorraine  
**Sent:** Tuesday, February 28, 2017 11:28 AM  
**To:** MaryAnn Lamb <MaryAnn.Lamb@bpl-us.com>  
**Subject:** BLA 125644 Proprietary Name Request and FPI  
**Importance:** High

Dear Dr. Lamb,

We are reviewing your submission for BLA 125644 Human Albumin Solution (HAS) 5% and 25%; we request the following information to continue our review:

Please submit a Proprietary Name Request (PNR) as an amendment to BLA 125644.

Also, please submit the Full Prescribing Information (FPI) to this submission.

Please contact me with any questions.

Thank you  
Lorraine

**Lorraine D. Wood, MS, MLS(ASCP)<sup>CM</sup>**  
*Regulatory Project Manager*

Center for Biologics Evaluation and Research  
Office of Blood Research and Review  
U.S. Food and Drug Administration  
Tel: 240-402-8439  
[lorraine.wood@fda.hhs.gov](mailto:lorraine.wood@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 notify the sender immediately by e-mail or phone.