

**From:** Wood, Lorraine  
**Sent:** Friday, April 20, 2018 10:15 AM  
**To:** 'MaryAnn Lamb' <MaryAnn.Lamb@bpl-us.com>  
**Subject:** Information Request for BLA 125644: Second Postmarketing Commitment: Response Requested by 4/27/18  
**Importance:** High

*Email*

STN: 125644

Applicant: Bio Products Laboratory

Product: Human Albumin Solution (HAS) 5% and 25%

Dear Dr. Lamb,

The agency request the following postmarketing commitment for BLA 125644:

PMC#2

2. Bio Products Laboratory Inc. commits to perform method validation for the determination of (b) (4) for intermediate precision using well characterized standards to establish valid range, repeatability, linearity and precision. In-process samples from the (b) (4) and final product samples should be tested against the result obtained using the established standards. Bio Products Laboratory Inc. will submit the results from the validation within six months of approval.

Final Report Submission: December 19, 2018

Please let me know if BPL agrees with this postmarketing commitment by submitting your response as an amendment to this BLA by close of business Friday April 27, 2018.

Thank you  
Lorraine

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

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