

*Sent By 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#1

1. Bio Products Laboratory commits to provide study results for leachables evaluated at the final shelf life for drug product Albuminex (Human Albumin Solution ) 5% and 25% as a post marketing commitment, submitting study results within 36 months of approval.

Final Report Submission: June 1, 2021

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 20, 2018.

Thank you  
Lorraine

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

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