

From: Wood, Lorraine
Sent: Wednesday, March 28, 2018 4:26 PM
To: 'MaryAnn Lamb' <MaryAnn.Lamb@bpl-us.com>
Subject: Information Request for BLA 125644: Response Requested by 4/4/18
Importance: High

Sent By Email

STN: BLA 125644/0

Applicant: Bio Products Laboratory

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

Dear Dr. Lamb,

We are reviewing your submission for BLA 125644 and we request the following information to continue our review:

1. In your response to our request for detailed description of the test method for NAT testing, you stated “Given that Albumin is manufactured from the same (b) (4) plasma derived product is it sufficient to cross refer back to the BLA for (b) (4) where information resides specific to these NAT tests for (b) (4), HBV, HCV, HIV-1 and B19, performed by (b) (4) on the (b) (4) ?” However, you have not provided the necessary specific details/references for locating the information including, Document name, Document number and Module number in the BLA submission package for (b) (4). Please provide detailed reference as necessary for us to locate the information or please submit the requested information for the NAT test in our previous IR (dated 01/17/2017) to permit us to review your BLA submission.
2. In module 3.2.S.2.3 – Control of Materials, you stated the validation data of the viral screening tests is in 3.2.S.4.3 – Validation of Analytical Procedures. We did not find the data in your submission. Please submit the necessary validation data of the NAT tests from each of the companies.

Please respond to this request by April 4, 2018.

Thank you
Lorraine

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