

From: Wood, Lorraine
Sent: Tuesday, February 28, 2017 11:01 AM
To: MaryAnn Lamb <MaryAnn.Lamb@bpl-us.com>
Subject: Information Request for BLA 125644 HAS: NAT
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:

1) In your response to our request for detailed description of the test method for NAT testing, you indicated "... 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)

?" However, you have not provided the necessary specific details/references for locating the information including, Document name, Document number and Module number in the 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. Rather you stated in section 1.3 of 3.2.S.4.3 that NAT tests were performed by outside contractors, (b) (4) and provided no other information. Please submit the necessary validation data of the NAT tests from each of the companies.

3) In module 3.2.S.4.4 – Batch Analysis – you stated "the Drug Substance Specification had not been formally introduced through the Quality Management System". Please clarify what that means. Are the Drug Substance specifications part of this BLA for review and approval?

Thank you
Lorraine

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