

From: Wood, Lorraine
Sent: Thursday, January 19, 2017 6:14 PM
To: MaryAnn Lamb <MaryAnn.Lamb@bpl-us.com>
Subject: Information Request for BLA 125644: HAS 5% and 25%
Importance: High

Dear Dr. Lamb,

We are reviewing your submission for BLA 125644/0 Human Albumin Solution (HAS) 5% and 25% and we request the following information to continue our review:

1. In section 3.2.S.4.2 Analytical Procedures, 1.2 NAT tests for (b) (4), HBV, HCV HIV-1 and B19, it states the NAT tests were performed by (b) (4) on the (b) (4). In order for us to continue our review please submit detailed description of the method that was utilized for NAT Tests.

Please contact me if you have any questions.

Sincerely,
Lorraine

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