

From: Wood, Lorraine
Sent: Tuesday, March 13, 2018 7:54 AM
To: 'MaryAnn Lamb' <MaryAnn.Lamb@bpl-us.com>
Subject: Information Request for BLA 125644: Response Requested by 3/26/18
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. Regarding your response to the CR Letter Item # 9 received on December 18, 2017; You stated in Table No. 10 on page 22 that the (b) (4)

However, it is unclear what the root cause and the resolution to prevent further temperature excursions during routine manufacturing. Please indicate the root cause for this incident and the resolution to prevent further temperature excursions during routine manufacturing.

2. Regarding your response to the CR Letter Item # 23.a. received on December 18, 2017;

You stated in Section 1.0 from CCIR/732/0/02/01 and CCIR/732/0/01/02, that Container Closure Integrity Testing (CCIT) was conducted to corroborate that there are no changes in the stoppering and crimping steps after the implementation of the new filling line ((b) (4)). Also, you indicated in these reports that this line is used for the manufacture of US licensed products. However, it is unclear when this line was approved for this purpose. Please provide the STN with approval date in support for the filling of US licensed products in the filling line (b) (4)

Please respond to this request by Monday March 26, 2018.

Thank you
Lorraine

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