

From: Wood, Lorraine
Sent: Monday, May 21, 2018 3:19 PM
To: 'MaryAnn Lamb' <MaryAnn.Lamb@bpl-us.com>
Subject: Container Labels for BLA 125644: Response Requested by 5/25/18
Importance: High

Sent by Email

Applicant: Bio Products Laboratory

STN: 125644/0

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

Dear MaryAnn,

Please submit the container labels for BLA 125644 Human Albumin Solution (HAS) 5% and 25%. We have the carton labels and the package insert but we do not have the labels that will go on the container vials. Please submit the vial container labels as an amendment to the file. If the container labels were already submitted, please let me know where we can locate the container labels in the submission.

Please respond to this request by COB Friday May 25, 2018.

Sincerely,
Lorraine

Lorraine D. Wood, MS, MLS(ASCP)^{CM}

Regulatory Project Manager

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