

From: Wood, Lorraine
Sent: Thursday, March 23, 2017 10:51 AM
To: MaryAnn Lamb <MaryAnn.Lamb@bpl-us.com>
Subject: Information Request for BLA 125644: Leachables and Extractables
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:

Please submit the extractable and leachable studies results of (b) (4) in the final container. The study durations must cover the expiration date of the drug product.

Please respond to this request prior to May 24, 2017.

Thank you
Lorraine

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