

From: Wood, Lorraine
Sent: Monday, March 06, 2017 12:36 PM
To: MaryAnn Lamb <MaryAnn.Lamb@bpl-us.com>
Subject: Information Request for BLA 125644: Response Requested by March 10, 2017
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) Was the equipment used for (b) (4) manufacture previously used to manufacture of Albumin lots?
- 2) Please submit validation data for all equipment used to include heat pasteurization, filling apparatus (b) (4) ?
- 3) Please describe the location of all manufacturing equipment and manufacturing steps for (b) (4) that are part of the manufacturing process as a manufacturing flow diagram, or as a series of diagrams.
- 4) Please submit a table, or manufacturing flow diagram that outlines each manufacturing step, the equipment associated with each step and its location in the manufacturing site.
- 5) Please submit a table showing all in-process controls associated and the manufacturing step with which it is associated.
- 6) Please submit complete batch records for all conformance lots.
- 7) Please submit a report listing all deviations and out of specification results that occurred during validation studies for (b) (4) 5% and 25%.

Please respond to this request by Friday March 10, 2017.

Thank you
Lorraine

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