

From: Wood, Lorraine
Sent: Wednesday, April 26, 2017 12:15 PM
To: MaryAnn Lamb <MaryAnn.Lamb@bpl-us.com>
Subject: Information Request for BLA 125644: Sections 3.2
Importance: High

Dear Dr. Lamb,

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

- 1) Section 3.2.S.3.1 ((b) (4) and other characteristics):
 - a) Please provide all raw data including (b) (4) used to determine (b) (4) of drug substance.
 - b) Please provide a detailed description of how (b) (4) performs (b) (4) for determining (b) (4)
- 2) Section 3.2.S.3.2 (Impurities)
 - a) Please provide raw data including figures representing (b) (4) for the (b) (4) step used to remove impurities.
 - b) Please provide raw data for the (b) (4) assay for each impurity. Include standard curve data used to quantify each impurity.
- 3) Section 3.2.S.4 (Specifications)
 - a) Please provide a detailed justification for specifications related to (b) (4) (Table 1).
 - b) Please provide raw data and figures for batch Process QC results listed Tables 3 and 6.
- 4) Section 3.2.S.7 (Stability Summary and Conclusions)
 - a) The stability summary and conclusions are incomplete. Only 5% HAS drug substance stability data (representing (b) (4)) has been submitted for (b) (4) time intervals up to (b) (4). Long term stability studies should be performed for both 5% and 25% HAS under normal and accelerated storage conditions. If available please provide long

term stability data for both 5% and 25% HAS drug substance with parameters, temperature conditions and time points in accordance with ICH guidelines.

5) Section 3.2.P.8 (Product stability Data)

- a) Limited stability data is available on HAS 5% and HAS 25% final products. Please provide updated drug product stability data for all manufacturing scale and pilot batches for both 5% and 25% HAS.
- b) In order to review the BPL established sampling and testing arrangement, please provide stability protocols SSP/00141 (manufacturing scale batches) and SSP/00138 (pilot scale batches).

Please respond to this request by May 10, 2017.

Thanks
Lorraine

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

Regulatory Project Manager

Center for Biologics Evaluation and Research
Office of Blood Research and Review
U.S. Food and Drug Administration
Tel: 240-402-8439
lorraine.wood@fda.hhs.gov



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