

From: Wood, Lorraine

Sent: Monday, February 06, 2017 2:53 PM

To: MaryAnn Lamb <MaryAnn.Lamb@bpl-us.com>

Subject: Information Request for BLA 125644 HAS: Validation Reports: Response Requested by 02/28/17

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. Validation of (b) (4) HIV 1+2 Test

- a. The description in the Analytical Procedure in 3.2.S.4.2 of Module 3 document is too brief to permit review. Please provide the SOP's for the test using (b) (4) [REDACTED] HIV 1/2 kits . Please provide the criteria in which you use one kit or the other.
- b. With reference to Table 2 on page 4 of document 3.2.S.4.3 Validation of Analytical Procedures, for the specificity of the (b) (4) [REDACTED] with (b) (4) [REDACTED] please provide the amount of HIV you spiked the sample with. Explain why the (b) (4) [REDACTED] difference is acceptable in the spiked samples vs. the normal human serum when there was negligible difference with the unspiked samples.
- c. With reference to Table 1 on page 3 of document 3.2.S.4.3 for Detection Limit of (b) (4) [REDACTED] and Table 5 on page 7 of the same document for Detection Limit of (b) (4) [REDACTED] HIV 1/2, please provide the data for the detection limit determination.
- d. With reference to Table 3 on page 5 of document 3.2.S.4.3 for the Robustness-Inter assay Variability please provide of the experimental design of your inter assay variability study.
- e. Provide the validation protocol for this method.

2. Validation of (b) (4) [REDACTED] Test

- a. The description in the Analytical Procedures 3.2.S.4.2 of Module 3 document is too brief to permit review. Please provide the SOP's for the (b) (4) [REDACTED] Test along with the confirmatory testing and the (b) (4) [REDACTED] test and confirmation. Provide the circumstances in which you use each kit.
- b. With reference to Table 9 on page 10 of document 3.2.S.4.3 Validation of Analytical Procedures, for the detection limit of the (b) (4) [REDACTED] test and Table 14 for the detection limit of the (b) (4) [REDACTED] , provide the data for the detection limit determination.

- c. With reference to Table 12 on page 11 of document 3.2.S.4.3 for the Robustness – Inter assay variability of the assay using (b) (4) kit provide the (b) (4) values to permit our review.
- d. With Reference to Table 11 for the specificity of the (b) (4) Confirmatory kit you stated on page 11, “(b) (4) is unlikely to be due to (b) (4) in the sample.” Provide data to support that statement.
- e. On page 11 you also stated, “the cause of the (b) (4) may have been caused during the preparation of the sample or by operator error when the test was run.” Have you investigated this? Please provide your investigation that this assumption is correct. If you have not investigated this, please provide your reason for not investigating.
- f. Provide the method validation protocol for (b) (4) test.

Please respond to this request by Tuesday February 28, 2017.

Sincerely,
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



THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please notify the sender immediately by e-mail or phone.