

Rana, Pratibha

From: Rana, Pratibha
Sent: Thursday, April 07, 2011 4:36 PM
To: 'Matthew Vaughn'
Subject: STN 125389/0 Information Request III/ April 7 2011

To: Matthew Vaughn
Biotest Pharmaceuticals Corporation

This is regarding your BLA submission STN 125389/0 for Immune Globulin Intravenous (Human), submitted to the Agency on November 3, 2010. FDA continues with the review of the referenced submission and requests BPC to provide the following information.

1. Since the viral validation studies were done at different locations by Biotest or (b)(4) please submit a summary to indicate the LRF values of all viruses tested at each location and the differences, if any, in the testing methods.
2. In your viral validation study for the S/D treatment, the WNV reduction value of (b)(4) is claimed in the overall LRF table instead of the value of 4.96 log₁₀. If higher value was obtained under the influence of downstream (b)(4), please provide related validation data to demonstrate the combined effects of these two steps on the WNV reduction or validate these two steps separately.
3. Please select the lower values for your claims of virus reduction in your overall LRF table. In addition, please take the value of bench controls into consideration when the final reduction values are calculated.
4. Please provide SOP SV-T: EV-043-01/ concerning the virus stock preparations and conditions.
5. Please provide SOP SV-T: EV-137-00/ concerning (b)(4)

Please submit a response to this request as an amendment to the file by May 9, 2011.

Thank you.

Pratibha Rana

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