

Rana, Pratibha

From: Rana, Pratibha
Sent: Friday, April 08, 2011 6:56 PM
To: 'Matthew Vaughn'
Subject: STN 125389/0 Information Request II/ April 8 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. Glycine concentration in Bivigam® is higher than some other IGIV products in the market. Please submit a toxicological assessment on the clinical safety of glycine.
2. How is the “worse case scenario” concentration of (b)(4) for TNBP (report number be-008-91) and TritonX (report number be-009-91) calculated?

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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