

Rana, Pratibha

From: Rana, Pratibha
Sent: Friday, July 22, 2011 1:16 PM
To: 'Matthew Vaughn'
Subject: STN 125389/0 Information Request

Attachments: BIVIGAM draft July 20_clean.doc

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. Please review the attached draft PI and provide comments to the CBER as early as possible.
2. Please provide the investigation report for the deviations regarding your new (b)(4)
3. Please provide the validation package for your new (b)(4).



BIVIGAM draft July
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Please submit a response to this request as an amendment to the file.

Thank you.

Pratibha Rana

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Regulatory Project Manager

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