

Rana, Pratibha

From: Rana, Pratibha
Sent: Thursday, February 10, 2011 11:23 AM
To: 'Matthew Vaughn'
Subject: STN 125389/0 Information Request

Dear Matt,

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. In your reports of "infection of any kind or seriousness" you report N=57, but there is no explanation as to why N does not equal 58, as it does for all other ITT population analysis. Please explain the reason for the discrepancy.

2. Please provide all information available to you on subject (b)(6)

Please submit a response to this request as an amendment to the file by February 17, 2011.

Thank you.

Pratibha Rana

Pratibha Rana, M.S.

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