

Rana, Pratibha

From: Rana, Pratibha
Sent: Friday, April 13, 2012 12:27 PM
To: 'Matthew Vaughn'
Subject: STN 125389/0 Information Request (4-13-2012)

Attachments: bivigam-pii-annotated.doc

Dear Matt,

This is regarding your BLA submission STN 125389/0 for Immune Globulin Intravenous (Human). FDA continues with the review of the referenced submission and requests BPC to make the labeling changes as per draft labeling (word document) attached with this email.



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Please submit a response to this request as an amendment to the file by April 16, 2012.

Thank you.

Pratibha
Pratibha Rana, M.S.
Regulatory Project Manager

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