

## Rana, Pratibha

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**From:** Rana, Pratibha  
**Sent:** Monday, April 02, 2012 2:55 PM  
**To:** 'Matthew Vaughn'  
**Subject:** STN 125389/0 Information Request

**Attachments:** bivigam-pi current.track changes.4.2.2012.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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current.track chang..

Please submit a response to this request as an amendment to the file by April 6, 2012.

Thank you.

Pratibha  
Pratibha Rana, M.S.  
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