

## Rana, Pratibha

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**From:** Rana, Pratibha  
**Sent:** Wednesday, July 18, 2012 12:08 PM  
**To:** 'Gary Ingenito'  
**Subject:** STN 125389/0 Information Request

Dear Gary,

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 provide the following information.

With respect to number 4:

Your description of the defect set used to qualify the 100 percent visual inspection procedure for Bivigam is sufficient. However, you have not provided complete qualification/validation data for the visual inspection program. As this is part of your license for the product, information demonstrating a validated visual inspection program is required to be present within your BLA. Therefore, please submit this information to your BLA.

Please submit a response to this request as an amendment to the file as soon as possible.

Thank you.  
Pratibha Rana

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