

## Rana, Pratibha

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**From:** Rana, Pratibha  
**Sent:** Tuesday, April 24, 2012 2:12 PM  
**To:** Matthew Vaughn  
**Subject:** STN 125389/0 Information Request ( 4-24-2012)

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 provide the following information.

1. Please modify the definition of hypotension to include the following additional clinical symptoms: chest pain, diaphoresis, change in the infusion rate. Thus, the definition should read “a decrease of 30mmHg **or** a SBP less than 90mmHg **and** clinical symptoms of hypotension. The clinical symptoms of hypotension include 1 or more of the following: dizziness or lightheadedness, fainting, chest pain, diaphoresis, or a change in the infusion rate.”
2. The FDA acknowledges that healthcare providers will administer the infusions and that an independent party will adjudicate the cases. Please identify the principal investigator. In other words, please identify the person responsible for data analysis and writing the study reports.
3. Please provide the protocol for vital sign measurements once an infusion service provider is selected. Please clarify that this protocol will include an assessment of the patient at 1 hour post-infusion. This could include vital sign measurements or simply a clinical assessment stating “no clinical signs of hypotension present, including dizziness, lightheadedness, chest pain, or diaphoresis.”
4. Please provide a copy of the study protocol when available. It would seem reasonable to have a draft protocol within 3 months and a final protocol within 6 months. If this is not possible, please suggest an alternate schedule.

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

Thank you.

Pratibha Rana  
Pratibha Rana, M.S.  
Regulatory Project Manager

FDA/CBER/OBRR  
Division of Blood Applications  
1401 Rockville Pike  
Rockville, MD 20852  
Office: (301) 827-6124  
Fax: (301) 827-2857  
email: pratibha.rana@fda.hhs.gov

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