

## Rana, Pratibha

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**From:** Rana, Pratibha  
**Sent:** Friday, April 08, 2011 10:27 AM  
**To:** 'Matthew Vaughn'  
**Subject:** STN 125389/0 Information Request/ April 8 2011

**To: Matthew Vaughn**  
**Biotest Pharmaceuticals Corporation**

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. Your study has a total of ten pediatric subjects which is inadequate for licensure for a pediatric indication. In general, 20 pediatric subjects ages 2 – 16 should be studied for pediatric indication.
2. You have requested a waiver for < 2 years of age and 2 – 5 years of age. FDA denies your request. Please amend your submission to include pediatric deferral for ages 2 – 16 and submit a pediatric plan that adds 10 more subjects ages 2 – 16 (5 pediatric subjects ages 2 – 5 and 5 ages 6 – 16).
3. FDA considers Subject (b)(6) to meet the criteria of a SBI. Please reanalyze the primary efficacy endpoint taking this subject into consideration. In addition, please recalculate all other parameters that may be affected by including this subject in the primary efficacy analysis (e.g., time to first SBI).
4. Please submit a spreadsheet extracted from Appendix 16.2.7 which includes all subjects who experienced a drop in systolic blood pressure of 20 mmHg or more during any infusion. Please include in this spreadsheet the following:
  - a. Medical history
  - b. Any symptoms reported during the infusion
  - c. A denotation of the exact time the infusion began
  - d. Whether the rate of infusion was changed at any time and during the changes in the blood pressure.

Please submit a response to this request as an amendment to the file by April 25, 2011.

Thank you.

Pratibha Rana

Pratibha Rana, M.S.  
Regulatory Project Manager

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