

## Rana, Pratibha

---

**From:** Rana, Pratibha  
**Sent:** Friday, April 20, 2012 11:59 AM  
**To:** 'Matthew Vaughn'  
**Subject:** STN 125389/0 Information Request ( 4-20-2012)

**Attachments:** bivigam-pi.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.



bivigam-pi.doc (293 KB)

Please submit a response to this request as an amendment to the file by April 23, 2012.

Thank you.

Pratibha  
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

"THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender immediately by e-mail or phone."