

## Rana, Pratibha

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**From:** Rana, Pratibha  
**Sent:** Thursday, June 21, 2012 3:38 PM  
**To:** 'Gary Ingenito'  
**Subject:** STN 125389/0 Information Request ( 6/21/2012)

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 5a:

1. For cleaning validation acceptance criteria for (b)(4) equipment, please consider using a (b)(4) limit of (b)(4).

With respect to number 5c:

2. Please submit complete cleaning validation final reports for all equipment specified in this CR question.

Please submit a response to this request to an amendment to the file by June 28, 2012.

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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