

Rana, Pratibha

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.
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