

Rana, Pratibha

From: Rana, Pratibha
Sent: Monday, June 11, 2012 5:20 PM
To: Gary Ingenito
Subject: STN 125389/0 Information Request (6/11/2012)

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.

1. Please provide a complete listing of Bivigam lots made to date. Please include manufacture date (final Bulk), shipping date, filling date, and the date lot was ready for release. Also, please include information on bulks not yet filled and filled lots not yet ready for release.
2. Please provide a sample for testing for every lot possible except lots where a sample has already been submitted for testing.

The address for samples is:

Attn. Christine Anderson/Nancy Eller/Dorothy Scott
Building 29/Room 232
8800 Rockville Pike
Bethesda MD 20892

Telephone numbers: 301-827-0173/301-928-2993//301-496-4396

If your staff can send us the carrier and tracking number information at the time of shipment, it will help us to make sure the samples arrive in a timely fashion.

Please submit a response to this request to an amendment to the file by June 18, 2012.

Thank you.
Pratibha Rana

Pratibha Rana, M.S.
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