

Rana, Pratibha

From: Rana, Pratibha
Sent: Wednesday, March 02, 2011 1:02 PM
To: Anupama Surapaneni
Cc: 'Matthew Vaughn'
Subject: STN 125389/0 Information Request
Importance: High

To: Matthew Vaughn
Biotest Pharmaceuticals Corporation
Date: March 2, 2011

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. In Appendix 16.2.14.1.1 you have plasma concentrations vs time data for total IgG and serotypes. In this Table you have provided only few concentrations for total IgG for a given subject. Please provide full data for total IgG concentrations in each and every subject in which you conducted PK study.

Please submit a response to this request as an amendment to the file by March 9, 2011.

Thank you.

Pratibha Rana