

Rana, Pratibha

From:
Sent:
To:
Subject:

To: Matthew Vaughn
Biotest Pharmaceuticals Corporation
Date: December 10, 2010

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.

Please provide the following information regarding your viral NAT assays:

1. Will you be using Source Plasma only for the manufacture of Biotest-IGIV? Or are you planning to use recovered plasma as well and/or in combination with Source Plasma?
2. What is the current status with regards to screening HIV, HBV, HCV, parvovirus B19 and HAV in terms of minipool and manufacturing pool testing?
3. Please provide the pool sizes, NAT sensitivities, and cut-off levels for minipool testing and original single plasma donation for each of these viruses.
4. Please provide the pool sizes, NAT sensitivities and cut-off levels for manufacturing pool testing for each of these viruses.
5. Please confirm that the parvovirus B19 DNA limit for each of your manufacturing pools for the production of Biotest-IGIV is set not to exceed 10^4 IU/mL.
6. Please provide a detailed summary about how the quarantine and proper disposal of NAT- positive donations for HIV/HBV/HCV/B19/HAV are done.

Please submit a response to this request as an amendment to the file by January 3, 2011.

Thank you.

Pratibha Rana

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