

Bioresearch Monitoring Mid-Cycle Review Memo, March 15, 2011 - Bivigam

DATE: March 15, 2011

FROM: Lillian Ortega, Bioresearch Monitoring, HFM-664
Division of Inspections and Surveillance
Office of Compliance and Biologics Quality

THROUGH: Pat Holobaugh, Bioresearch Monitoring Branch Chief, HFM-664

TO: Michael Kennedy, HFM- 345, Chair person, BLA Committee
Mitchell Frost, HFM-392, Clinical Reviewer, BLA Committee
Pratibha Rana, HFM-380, RPM, BLA Committee

SUBJECT: Bioresearch Monitoring Mid-Cycle Review
BLA/STN: 125389/0

Sponsor: Biotest Pharmaceuticals Corporation
Product: Immune Globulin Intravenous (Human) 10% (Nabi- IGIV)

Bioresearch Monitoring clinical investigator inspection assignments were issued on December 20, 2010 for the following study sites:

Site	Study Site	Location	Subjects
007	Children's Hospital Los Angeles	Los Angeles, California	7
009	Montefiore Medical Center	Bronx, New York	5
014	Bellingham Asthma, Allergy & Immunology Clinic	Bellingham, Washington	5
019	Allergy & Asthma Center	Toledo, Ohio	8

The above inspections are pending completion. The requested completion date for the inspections is March 28, 2011. We will tell the committee about the results of the inspections as soon as they are available. Should you have any questions about this memo or any aspects of Bioresearch Monitoring, please contact me at 301-827-6335.

/s/

Lillian Ortega
Consumer Safety Officer