

# Waiver Memo - Bivigam

Department of Health and Human Services  
Food and Drug Administration  
Center for Biologics Evaluation and Research  
Office of Compliance and Biologics Quality  
Division of Manufacturing and Product Quality

## MEMORANDUM

To: File, BL STN 125389/0  
From: Destry Sillivan, Acting Branch Chief, OCBQ/DMPQ/MRB II, HFM-676  
Subject: Recommendation to waive a pre-license inspection  
Sponsor: Biotest Pharmaceuticals Corporation (US License # 1792)  
Product: Immune Globulin Intravenous (Human) 10%  
Indication: Primary Immune Deficiency Disorders (PIDD)  
Through: Laurie Norwood, Deputy Director, OCBQ/DMPQ/ HFM-676  
CC: Pratibha Rana, RPM, DBA/OBRR, HFM-380  
CC: Damaris Lopez-Rosario, CSO, OCBQ/DIS/PSB, HFM-656

## Concurrent Clearance Routing

\_\_\_\_\_ **Date:** \_\_\_\_\_  
John A. Eltermann, Jr., R.Ph., \_\_\_\_\_  
M.S. CONCUR DO NOT CONCUR  
Director, Division of Manufacturing and Product Quality, HFM-670  
Office of Compliance and Biologics Quality, CBER

\_\_\_\_\_ **Date:** \_\_\_\_\_  
Basil Golding, MD \_\_\_\_\_  
NOT CONCUR CONCUR DO  
Director, Division of Hematology, HFM-345  
Office of Blood Research & Review, CBER

## Summary

I recommend that a pre-license inspection (PLI) be waived for Biotest's facility located at 5800 Park of Commerce Blvd, N.W. Boca Raton, Florida 33487, where Immune Globulin Intravenous (Human) 10% is manufactured under the BLA STN 125389/0, based on CBER SOPP 8410 "Determining When Pre-License/Pre-Approval Inspections (PLI/PAI) Are Necessary."

## Background



I recommend waiving the PLI for the Biotest facility referenced in this BLA based on the information provided in the BLA, the previous inspection report and related correspondence supporting the overall compliance status of the license holder.

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CDR Destry Sullivan, USPHS  
Acting Branch Chief/CMC-Facility reviewer  
CBER/OCBQ/DMPQ/MRB II, HFM-676

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Michael Kennedy, Ph..D.  
CMC chair  
CBER/OBRR/DH/LPD, HFM-345

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