

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 Sullivan, 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

<u>Date:</u>	_____	_____
John A. Eltermann, Jr., R.Ph., M.S. Director, Division of Manufacturing and Product Quality, HFM-670 Office of Compliance and Biologics Quality, CBER	CONCUR	DO NOT CONCUR

<u>Date:</u>	_____	_____
Basil Golding, MD NOT CONCUR Director, Division of Hematology, HFM-345 Office of Blood Research & Review, CBER	CONCUR	DO

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

Biotest submitted a BLA on November 11, 2010, STN 125389/0, for the manufacture of Immune Globulin Intravenous (Human) 10%, a highly purified, sterile, liquid preparation of concentrated human immunoglobulin G (IgG) antibodies, using a modified Cohn/Oncley process at their facility located in Boca Raton, FL .

FDA last inspected this Biotest facility on May 9-17, 2012. This inspection was determined to be Voluntary Action Indicated per FACTS Biotest FEI 1000525461.

Basis for the Waiver

This waiver is based on criteria outlined in the Center-wide SOPP 8410 "Determining When Pre-License/Pre-Approval Inspections (PLI/PAI) Are Necessary." As stated in the aforementioned SOPP, it is CBER's policy that a PLI or PAI will generally be necessary for a BLA if any of the following criteria **in bold** are met:

- **The facility does not hold an active US license.**

Biotest holds a current US license number 1792.

- **The facility has not been inspected in the last two years by the FDA.**

Biotest facilities have been inspected within the last two years by FDA, as noted above. This inspection, completed by Burnell Henry of Team Biologics during the period of May 9-17, 2012, was classified as Voluntary Action Indicated.

- **The establishment is performing significant manufacturing step(s) in new (unlicensed) areas using different equipment (representing a process change). This would include areas that are currently dedicated areas that have not been approved as multi-product facilities/buildings/areas.**

Biotest, U.S. License # 1792, is manufacturing Immune Globulin Intravenous (Human) 10% in the same licensed facility using equipment shared with -----(b)(4)-----

----- Immune Globulin Intravenous (Human) 10% is manufactured in areas used exclusively for the manufacture of human Immunoglobulin products.

- **The previous inspection revealed significant GMP deficiencies in areas related to the processes in the application/supplement (similar processes) or systemic problems, such as QC/QA oversight.**

The most recent surveillance inspection of Biotest in May of 2012 was classified as Voluntary Action Indicated. The cited deficiencies in these inspections were deemed not significant or no systemic impairment to be in compliance with applicable standards.

- **The manufacturing process is sufficiently different (new production methods, specialized equipment or facilities) from that of other approved products produced by the establishment.**

Immune Globulin Intravenous (Human) 10% is manufactured at Biotest using a -----
----- (b)(4) -----.

Waiver Recommendation

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.

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

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