



U.S. FOOD & DRUG
ADMINISTRATION

DATE: April 25, 2024

FROM: Haecin Chun, MS, Consumer Safety Officer
Bioresearch Monitoring Branch (BMB)
Division of Inspections and Surveillance (DIS)
Office of Compliance and Biologics Quality (OCBQ)

THROUGH: Dennis T. Cato, Associate Director, Bioresearch Monitoring (BIMO)

THROUGH: Carrie M. Mampilly, MPH, Director, DIS

TO: Jennifer Reed, PhD, Chair, BLA 125810/0
Afsah Amin, MD, MPH, Clinical Reviewer
Elizabeth Hart, MD, Clinical Reviewer
Mona Badawy, RPM

SUBJECT: BIMO Final Discipline Review Memo

SPONSOR: Biotest AG
PRODUCT: Immune Globulin Intravenous, Human, 10% Liquid, IgG Next Generation
Application: BLA 125810/0

FINAL SUMMARY STATEMENT

BIMO inspection assignments were issued for one domestic and three foreign clinical investigator (CI) study sites that participated in the conduct of Protocol BT595-991. The inspections did not reveal significant issues that impact the data submitted in this original Biologics License Application (BLA).

BACKGROUND

Four BIMO CI inspection assignments (one domestic and three foreign study sites) were issued in support of this BLA. The clinical study sites were selected based on subject enrollment, previous inspection history, as well as the data and information submitted in BLA 125810/0.

The inspections focused on the study entitled, *“Phase 3, an open-label, prospective, multicenter study investigating clinical efficacy, safety, and pharmacokinetic properties of the human normal immunoglobulin for intravenous administration BT595 as replacement therapy in patients with primary immunodeficiency disease (PID)”* (Protocol BT595-991).

The inspections were conducted in accordance with FDA’s Compliance Program (CP) 7348.811, Inspection Program for CI. Information and data submitted in the BLA were compared to source documents at each inspected site. The inspection assignments also included specific questions concerning the pivotal study.

INSPECTION SUMMARY AND OUTCOME

The table below summarizes the BIMO inspections:

Site ID	Study Site Name and Location	483 Issued?	Final Classification
106	The South Bend Clinic South Bend, Indiana, U.S.A.	No	No Action Indicated (NAI)
3602	Del-pesti Centrumkorhaz - Orzagos Hematologiai es infektologiai Intezet Gyermekehematologiai es ossejttranszplantacios osztaly Budapest, Hungary	No	NAI
4905	Klinikum St. Georg Leipzig Klinik fuer Kinder- und Jugendmedizin Immun Defekt Centrum Leipzig (IDCL) Saxony, Germany	No	NAI
3603	Szabolcs-Szatmar-Bereg Megyei Korhazak es Egyetemi Oktatokorhaz Gyermekeosztaly Nyíregyháza, Hungary	No	NAI

Sponsor:

No significant sponsor issues were observed during the inspection.

Clinical Investigators:

No significant issues were observed during the CI inspections.

FINANCIAL DISCLOSURE:

The CI CP directs the FDA investigator to ask the CI if and when he/she disclosed information about his/her financial interests to the sponsor and/or interests of any sub-investigators, spouse(s) and dependent children, and if and when the information was last updated. The information submitted to the BLA was verified for each of the inspected parties.

ADMINISTRATIVE FOLLOW-UP:

An Field Management Directive (FMD)-145 Letter was issued to each foreign clinical investigator.

Should you have any questions or comments about the contents of this memo or any aspect of Bioresearch Monitoring, please contact me at haecin.chun@fda.hhs.gov.

Haecin Chun
Consumer Safety Officer