

Bioresearch Monitoring BLA Summary Report - Wilate, December 13, 2007

DATE December 13, 2007

FROM Solomon Yimam, Bioresearch Monitoring Branch, HFM-664
Division of Inspections and Surveillance
Office of Compliance and Biologics Quality

SUBJECT Bioresearch Monitoring BLA Summary Report
Octapharma AG

SPONSOR Seidenstrasse 2
CH-8852 Lachen, Switzerland

PRODUCT WILATE is a human plasma-derived, stable, high purity, double virus inactivated concentrate of freeze-dried FVIII and VWF. It is prepared using cryoprecipitate harvested from plasma collected in the U.S. WILATE is supplied as a powder for reconstitution and intravenous injection.

THROUGH Patricia Holobaugh
Bioresearch Monitoring Branch Chief, HFM 664

TO Timothy Lee, HFM-392
Chair, BLA/STN 125251

FINAL SUMMARY STATEMENT

Results of three bioresearch monitoring inspections of three clinical sites did not reveal problems that impact the data submitted in the application.

BACKGROUND

Inspections of three clinical investigators were performed in support of this Biologics License Application (BLA). Information from the BLA was compared to source documents during the inspections. The inspections focused on specific questions concerning the study.

STUDY TITLE: A Prospective, Randomized, Controlled, Open-labeled, Two-arm Crossover Study Investigating the Pharmacokinetic Properties of WILATE and Humate-P® in Subjects with Inherited von Willebrand Disease (WIL-12).

The clinical investigator inspections assigned included the following:

Clinical Investigator	Study Site	Location	FDA 483	Final Classification
Jerry S. Powell, MD	University of California at Davis Hemophilia Treatment Center	Sacramento, California	Yes	NAI
Arthur R. Thompson, MD, PhD	Puget Sound Blood Center	Seattle, Washington	NO	NAI

Clinical Investigator	Study Site	Location	FDA 483	Final Classification
Jorge DiPaolo, MD	University of Iowa Hospitals & Clinics Department of Pediatrics	Iowa City, Iowa	NO	NAI

INSPECTIONAL FINDINGS

The inspections of the three clinical investigators did not reveal any significant protocol deviations.

BIMO ADMINISTRATIVE FOLLOW-UP

Close out letters were issued to Dr. Jerry S. Powell, Dr. Arthur R. Thompson, and Dr. Jorge DiPaolo.

Should you have any questions or comments about the contents of this memorandum or any aspect of Bioresearch Monitoring, please contact me at (301) 827-1948.

Solomon Yimam
Consumer Safety Officer