

Final Review Memo (12/16/2008) - RiaSTAP

MEMORANDUM

DATE December 16, 2008

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

THROUGH Patricia Holobaugh, Bioresearch Monitoring
Branch Chief, HFM-664

TO Laura Wood, HFM-340, Chair, BLA Committee
Vasanth Kumar, HFM- 380, RPM, BLA
Committee

SUBJECT Bioresearch Monitoring Bioresearch Monitoring
Inspection Results
SPONSOR: CSL Behring GmbH
PRODUCT: Human fibrinogen concentrate,
pasteurized, Riastap™
BLA: STN 125317/0

SUMMARY STATEMENT:

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

BACKGROUND:

Three clinical investigator inspections were performed in support of this Biologics License Application (BLA). Information from the BLA was compared to source documents during the inspections.

CLINICAL INVESTIGATORS:

	Site #	# Subjects	483?	Inspection Classification
New York Presbyterian Hospital New York, New York	12	1	No	NAI
Children's Memorial Hospital Chicago, Illinois	15	1	No	NAI
Maine Hemophilia and Thrombosis Center Scarborough , Maine	19	1	No	NAI

STUDY TITLE: Pharmacokinetics of Haemocomplettan ® P in Subjects with Congenital Fibrinogen Deficiency (Study No. BI3023_2001)

SPONSOR ISSUES:

At two of the three inspected sites, the amount of study drug remaining after administration to Subject -(b)(6)- (42 ml) and Subject -(b)(6)- (25 ml) exceeded the expected amount. Both sites state the dose administered to the subjects was correct and the study drug was prepared according to the protocol. Clarification from the sponsor regarding this finding may be required.

NOTE WORTHY INSPECTIONAL FINDINGS:

The following required laboratory evaluations were not completed for Subject -(b)(6)-: One-hour post infusion Gamma-glutamyl transpeptidase (GGT), Day 2 GGT, Pre-infusion Platelets, and Day 5 Biochemistry.

BIMO ADMINISTRATIVE FOLLOW-UP:

Close out letters have been issued to the clinical investigators at the three inspected sites. Should you have any questions or comments about the contents of this memo or any aspect of Bioresearch Monitoring, please contact me at 301-827-6323.

Christine J. Drabick, MS
Consumer Safety Officer