Memorandum

DATE	June 1, 2018
FROM	Bhanu Kannan, Bioresearch Monitoring Branch Division of Inspections and Surveillance Office of Compliance and Biologics Quality Telephone: 240-402-8979 Fax: 301-595-1304
THROUGH	Dennis Cato, Chief, Bioresearch Monitoring Branch
THROUGH	Carrie Mampilly, M.P.H., Director, Division of Inspections and Surveillance
TO	Zuben Sauna, Ph.D., Chair, STN125661/0 Megha Kaushal, M.D., Clinical reviewer Olukayode Owosela, RPM Candace Jarvis, RPM
SUBJECT	Bioresearch Monitoring Final Review Memo
APPLICANT	Bayer Healthcare LLC.
PRODUCT	Antihemophilic factor (Recombinant), PEGylated
BLA	STN 125661/0

FINAL SUMMARY STATEMENT

Bioresearch Monitoring (BIMO) inspections of three domestic, and one foreign clinical investigator sites did not reveal substantive problems impacting the data submitted in support of this Biologics License Application (BLA).

Background

Four clinical investigators (CI) were inspected in support of this BLA. The inspections were conducted in accordance with FDA's Compliance Program Guidance Manual (CPGM) 7348.811, Inspection Program for Clinical Investigators. The inspection assignments were issued for the study protocol 13024:

A Phase II/III, multicenter, partially randomized, open label trial investigating safety and efficacy of on-demand and prophylactic treatment with BAY 94-9027 in Severe Hemophilia A-Study 13024

The inspection assignments included specific questions concerning the respective study protocol and information submitted in the BLA was compared to source documents at

the site. The CI inspections covered approximately 14% and 27% of the total subjects enrolled in Part A and Part B of the study, respectively.

The BIMO inspections were conducted at the following clinical sites:

Site Number	Number of Subjects	Location	Form FDA 483 issued	Final Classification
14002	10	Penn State Health Milton S. Hershey Medical Center Hershey, Pennsylvania	No	NAI
14013	3	SUNY Upstate Medical University Syracuse, New York	No	NAI
14024	3	University of California -Davis Sacramento, California	No	NAI
68001	6	Singapore General Hospital Singapore	No	NAI

NAI-No Action Indicated

Financial Disclosure

The Clinical Investigator Compliance Program directs the FDA investigators to ask the clinical investigator if and when he/she disclosed information about his/her financial interests to the sponsor and/or interests of any sub-investigators, spouses and dependent children, and if and when the information was updated. The information submitted to the BLA was verified at each of the inspected clinical sites and our inspections found no deviations in the submitted data.

Sponsor Issues

None noted.

Noteworthy inspectional findings

None noted.

BMB administrative follow-up

Information letters were issued to the clinical investigators inspected in support of this BLA. Should you have any questions about the contents of this memo or any aspect of BIMO, please contact me at 240-402-8979.

Bhanu Kannan
Consumer Safety Officer