Bioresearch Monitoring Discipline Review Memo, September 30, 2014 - TRUMENBA

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Biologics Evaluation and Research

DATE September 30, 2014

FROM Lillian Ortega, Bioresearch Monitoring Branch
Division of Inspections and Surveillance
Office of Compliance and Biologics Quality

THROUGH Patricia Holobaugh, Chief, Bioresearch Monitoring Branch,

THROUGH Gilliam Conley, Director, Division of Inspections and Surveillance

TO Drusilla Burns, BLA Committee Chair
Lucia Lee, Clinical Reviewer
Michael Smith, Lead Regulatory Project Manager
Theodore Garnett, Regulatory Project Manager
Ramachandra S. Naik, Regulatory Project Manager

SUBJECT Bioresearch Monitoring Discipline Review Memo
BLA: STN 125549/0
IND: 13812
PRODUCT: Meningococcal Group B Vaccine
SPONSOR: Wyeth Pharmaceuticals Inc. (a subsidiary of Pfizer, Inc.)

REVIEW SUMMARY

Bioresearch Monitoring inspections of three clinical investigators were conducted in support of this Biologics Licensing Application (BLA). The inspections did not reveal significant problems that impact the data submitted in this BLA.

BACKGROUND

Three clinical sites under Protocol B1971011 were identified for bioresearch monitoring inspections. The BLA review committee concurred with the proposed sites. The clinical sites were selected based upon the number of subjects enrolled, previous inspectional history, number and types of adverse events, number and types of protocol deviations, and geographic location.

Protocol Inspected: **B1971011** *A Phase 2, Randomized, Active- Controlled, Observer-blinded Trial, to Assess the Safety, Tolerability and Immunogenicity of Gardasil (HPV) Vaccine and a rLP2086 Vaccine When Administered Concomitantly in Healthy Subjects Aged ≥ 11 to <18 Years.*

Protocol B1971011 was conducted at 63 clinical sites in the U.S. A total of 2499 subjects were randomized and 2484 received the investigational product. The three inspected clinical sites comprise approximately 12% of the total subjects randomized under the protocol.

The inspections were conducted in accordance with FDA's Compliance Program Guidance Manual (CPGM) 7348.811, Inspection Program for Clinical Investigators. Information submitted in the BLA was compared to source documents at each clinical site. The inspection assignment included specific questions concerning the clinical study.

INSPECTION SITES:

Bioresearch Monitoring inspections were conducted at the following clinical sites:

Site Number for B1971011	Study Site	Location	Form FDA 483 Issued	Final Classification
1007	Kentucky Pediatric/Adult Research	Bardstown, Kentucky	No	NAI
1023	Jean Brown Research	Salt Lake City, Utah	Yes	VAI
1069	Advanced Pediatrics	Vienna, Virginia	No	NAI

SIGNIFICANT INSPECTIONAL FINDINGS:
No significant inspectional findings that would impact the validity of the data generated at the inspected sites were observed.

SPONSOR ISSUES
No sponsor or monitoring issues were noted.

FINANCIAL DISCLOSURE:
The Clinical Investigator Compliance Program directs the FDA investigator 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, spouse(s) and dependent children, and if and when the information was updated. The information submitted to the BLA was verified for each of the inspected clinical sites.

ADMINISTRATIVE FOLLOW-UP:
We issued information letters to each of the clinical investigators at study sites 1007 and 1069. An information letter will be issued to the clinical investigator at study site 1023. Should you have any questions or comments about the contents of this memo or any aspect of Bioresearch Monitoring, please contact me at 240-402-9041.

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Lillian Ortega
Consumer Safety Officer