Bioresearch Monitoring Inspection Results, June 12, 2009 - Menveo

M E M O R A N D U M DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Biologics Evaluation and Research

DATE June 12, 2009

FROM Janet White, 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 Willie Vann, Chair, BLA Committee, HFM-437

SUBJECT Bioresearch Monitoring Inspection Results

STN: BLA 125300/0

Sponsor: Novartis Vaccines & Diagnostics, Inc.

Product: Novartis Meningococcal ACWY Conjugate Vaccine

SUMMARY STATEMENT

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

BACKGROUND

Four clinical investigator inspections were performed in support of this Biologics License Application (BLA). Study subject population, geographic distribution, field resource considerations, and specific review committee concerns were among the factors used to select the inspected sites. The inspections focused on specific questions concerning one pivotal study and the comparison of information from the BLA to source documents.

Study Site	Site #	Location	Number of Subjects	Form FDA 483 Issued	Inspection Final Classification
Dartmouth Hitchcock Medical Center	44	Lebanon, New Hampshire	227	No	NAI
Kentucky Pediatric/ Adult Research Inc.	53	Bardstown, Kentucky	347	Yes	VAI
Primary Physicians Research, Inc.	*	Pittsburgh, Pennsylvania	774	Yes	VAI
Kaiser Permanente Med Group – Vaccine Study	**	Oakland, California	630	Yes	VAI

***** Sites: 12, 13, 14, 15, 16, 18, 19, 20, 21, 22, 23, 24, 25, 26, 51, 54

****** Sites: 6, 7, 8, 9, 10, 11

STUDY TITLE:

Protocol V59P13: A Phase 3, Randomized, Observer-blind, Controlled, Multi-Center

Study to Evaluate the Lot to Lot Consistency of Novartis Meningococcal ACWY Conjugate Vaccine when One Dose is Administered to Healthy Adolescents 11-18 Years of Age and to Compare the Safety and Immunogenicity of Novartis Meningococcal ACWY Conjugate Vaccine with that of Licensed Meningococcal ACWY Conjugate Vaccine (Menactra™) when One Dose is Administered to Healthy Subjects 11-55 Years of Age

SPONSOR ISSUES

No sponsor or monitoring issues were noted.

NOTEWORTHY INSPECTIONAL FINDINGS

There were only a few minor problems noted. At the Oakland, California site three protocol deviations were noted related to two subjects being enrolled who did not meet the inclusion/exclusion criteria and one blood sample not stored at the protocol required temperature. At the Pittsburgh, Pennsylvania site records of three of the eighty subjects audited were found with numbering errors; source documents were changed up to two months later; and a non-study vaccine was given to a subject within seven days of receiving the study vaccine and this was not documented on the concomitant medications case report form or reported to the sponsor as required by the protocol. At Site 53 records of eighteen of the eighty subjects audited were found with one or more of the following: discrepancies between the source documents and case report forms, missing data and/or signatures, and missing or incorrect dates and the close out report to the Institutional Review Board (IRB) did not accurately identify the noncompliant and lost to follow-up subjects.

BIMO ADMINISTRATIVE FOLLOW-UP

We issued inspection closeout letters to the clinical investigators at all four of the study sites. Please contact me at (301) 827-6336 if you have any questions about this memo or any aspect of bioresearch monitoring.

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Janet White
Consumer Safety Officer