



U.S. FOOD & DRUG
ADMINISTRATION

Memorandum

DATE: September 18, 2023

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Division of Inspections and Surveillance (DIS)
Office of Compliance and Biologics Quality (OCBQ)

THROUGH: Dennis T. Cato, Chief BMB

THROUGH: Carrie M. Mampilly, MPH, Director DIS

SUBJECT: Bioresearch Monitoring Discipline Review Memo

PRODUCT: Meningococcal Groups A, B, C, Y, W Vaccine

SPONSOR: Pfizer Ireland Pharmaceuticals
BLA STN: 125770/0

REVIEW SUMMARY

Bioresearch Monitoring (BIMO) Clinical Investigator (CI) inspection assignments were issued for four clinical study sites that participated in the conduct of protocol C3511001. The inspections did not reveal substantive issues that impact the data submitted in this Biologics License Application (BLA).

BACKGROUND

Four clinical study sites conducting the study protocol C3511001 were identified for BIMO CI inspections. The sites were selected based upon the inspectional history, sponsor-reported adverse events, protocol deviations, and total number of subjects enrolled.

The inspections were performed in accordance with FDA's Compliance Program (CP) 7348.811, Inspection Program for Cis. Information submitted in the BLA was compared to source documents at each inspected site. The inspection assignment also included specific questions concerning the clinical study protocol C3511001.

PROTOCOL

Protocol C3511001: A Phase 3, Randomized, Active-Controlled, Observer-Blinded Trial to Assess the Safety, Tolerability, and Immunogenicity of MenABCWY in Healthy Participants ≥ 10 to < 26 Years of Age.

The study randomized a total of 2,431 subjects in 5 countries. The inspected sites comprised of about 25% of the total subjects enrolled under protocol C3511001.

BIMO INSPECTIONS SUMMARY

No significant BIMO inspectional findings were noted for the completed inspections. The below table summarizes site information and outcomes from the BIMO inspections.

Study Site #	Firm Name	Location	FDA Form 483 Issued	Inspectional Final Classification
1004	Michael Simon, MD	Lexington, KY	No	NAI – No Action Indicated
1046	Alan Garscadden, MD	Colorado Springs, CO	Yes	VAI – Voluntary Action Indicated
1068	Aftab Naz, MD	Madera, CA	No	NAI
1136	Teena Hughes, MD	Tampa, FL	No	NAI

INSPECTIONAL FINDINGS:

For sites 1004, 1068 and 1136 there were no significant observations, and a Form FDA 483 was not issued at close of those inspections.

For Alan Garscadden, site 1046, a Form FDA 483 was issued for failure to maintain accurate reporting according to the protocol. Specifically, the CI failed to report full medical history for subject (b) (6) and not all adverse events were reported for subjects (b) (6), (b) (6) and (b) (6). The corrective action plan from the CI was reviewed and determined to be acceptable.

SPONSOR/MONITORING ISSUES

No significant sponsor or monitoring issues were identified during the inspections.

FINANCIAL DISCLOSURE

The CI CP directs the FDA investigator to ask the CI 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, as well as if and when the information was last updated. The information submitted to the BLA was verified for each of the inspected clinical study sites.

ADMINISTRATIVE FOLLOW-UP

Should you have any questions or comments about the contents of this memo or any aspect of Bioresearch Monitoring, please contact me at 301-796-6667.

Malcolm Nasirah, PharmD, MS, BCGP
Consumer Safety Officer

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Reviewed: Cato: 9.15.23
