Memorandum

DATE: April 14, 2023

TO: Goutam Sen, PhD, Chair
Paul Keller, PhD, RPM
Nadine Peart Akindele, MD, Clinical Reviewer

FROM: Peter Lenahan, DC, PhD, MPH, Regulatory Reviewer
Bioresearch Monitoring Branch (BMB)
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 Final Discipline Review Memo

PRODUCT: Respiratory Syncytial Virus (Rsv) Prefusion F Subunit Vaccine

SPONSOR: Pfizer, Inc.
BLA STN: 125769/0

FINAL SUMMARY STATEMENT

Bioresearch Monitoring (BIMO) inspections were issued for one domestic and two foreign clinical study sites that participated in the conduct of study Protocol C3671013. The inspections did not reveal substantive issues that impact the data submitted in this Biologics License Application (BLA).

BACKGROUND

The inspections were conducted in accordance with FDA's Compliance Programs (CP) 7348.811, Inspection Program for Clinical Investigators (CI) and (CP) 7348.810, Sponsors, Contract Research Organizations and Monitors. 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 C3671013.

PROTOCOL

C3671013; Title: *A Phase 3 Study To Evaluate The Efficacy, Immunogenicity, And Safety Of Respiratory Syncytial Virus (RSV) Prefusion F Subunit Vaccine In Adults was evaluated.*

The sponsor reported that this study was conducted at 240 sites world-wide; United States (158), South Africa (20), Japan (18), Canada (15), Finland (13), the Netherlands (12), and Argentina (4). As of the data cutoff date (14 July 2022), 34,383 participants were randomized to receive RSVpreF (17,197) or placebo (17,186).

BIMO INSPECTIONS SUMMARY

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

Study Site #	Location	FDA Form 483 Issued	Inspectional Final Classification
1121	Pembroke Pines, FL	No	No Action Indicated (NAI)
1290	Caba, Buenos Aires 1536 5b Argentina	No	NAI
1254	Caba, Buenos Aires 1426 Argentina	No	NAI

INSPECTIONAL FINDINGS:

No significant inspectional findings were observed.

SPONSOR/MONITORING ISSUES

No significant sponsor or monitoring issues were identified during the above 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 301-331-4947 or Peter.Lenahan@fda.hhs.gov.

Peter Lenahan, DC, PhD, MPH
Senior Regulatory Officer