



**U.S. FOOD & DRUG**  
ADMINISTRATION

## Memorandum

## Center for Biologics Evaluation and Research

DATE August 04, 2023

FROM Haecin Chun, MS, Consumer Safety Officer  
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 Mampilly, MPH, Director DIS

TO Goutam Sen, PhD, Chair  
Yugenia Hong-Nguyen, MD, Clinical Reviewer  
Paul Keller, PhD, RPM  
Laura Montague, RPM  
Vera Stupina, PhD, RPM

SUBJECT Bioresearch Monitoring Final Review Memo  
SPONSOR Pfizer, Inc.  
PRODUCT Respiratory Syncytial Virus Vaccine (ABRYSVO)  
BLA STN 125768/0

### FINAL SUMMARY STATEMENT

Bioresearch Monitoring (BIMO) inspections were issued for three clinical investigator (CI) study sites that participated the conduct of Protocol C3671008. The inspections did not reveal significant problems impacting the data submitted in support of this original Biologics License Application (BLA).

### BACKGROUND:

BIMO inspection assignments were issued for three clinical investigators to review the study conduct of a pivotal study entitled, “*A Phase 3, Randomized, Double-blinded, Placebo controlled Trial to Evaluate the Efficacy and Safety of a Respiratory Syncytial Virus (RSV) Prefusion F Subunit Vaccine in Infants Born to Women Vaccinated During Pregnancy*” (Protocol C3671008). The clinical study sites were selected based on subject enrollment, previous inspection history, and the other information submitted in the BLA with the review committee’s input.

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

#### INSPECTION SUMMARY AND FINDINGS:

No significant objectionable inspectional findings were observed. The table below summarizes the BIMO inspections at the following domestic clinical study sites:

Site ID	Study Site Location	FDA Form 483 Issued?	Final Inspection Classification
1020	MedPharmics, LLC Phoenix, AZ	No	No Action Indicated (NAI)
1030	East LA Doctors Hospital Los Angeles, CA	No	NAI
1058	Ventavia Research Group LLC Plano, TX	No	NAI

#### Clinical Investigator Issues:

No significant issues were observed during the inspection

#### Sponsor Issues

No significant sponsor issues were noted.

#### FINANCIAL DISCLOSURE

The CI CP directs the FDA investigators 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, spouses and dependent children, and if and when the information was last updated. The information submitted to the BLA was verified at the inspected clinical sites, and no deviations were found in the submitted data.

#### ADMINISTRATIVE FOLLOW-UP

Should you have any questions about the contents of this memo or any aspect of BIMO, please contact me at (b) (6).

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Haecin Chun, MS  
Consumer Safety Officer