



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

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## Memorandum

DATE: May 21<sup>st</sup>, 2021

TO: Christina Houck, BLA Committee Chair  
Tina Mongeau, MD, MPH, Clinical Reviewer  
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FROM: Malcolm Nasirah, PharmD, MS, Bioresearch Monitoring Branch  
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Office of Compliance and Biologics Quality

THROUGH: Dennis T. Cato, Chief, Bioresearch Monitoring Branch

THROUGH: Carrie M. Mampilly, MPH, Director, Division of Inspections and Surveillance

SUBJECT: Bioresearch Monitoring Final Discipline Review Memo

PRODUCT: 20-valent Pneumococcal Conjugate (20vPnC) Vaccine  
SPONSOR: Wyeth Pharmaceuticals LLC  
BLA STN: 125731/0

### REVIEW SUMMARY

Bioresearch Monitoring (BIMO) inspections were issued for three clinical study sites that participated in the conduct of study Protocol B7471007. The inspections did not reveal substantive issues that impact the data submitted in this Biologics License Application (BLA).

### BACKGROUND

Three U.S. clinical study sites conducting the phase III study Protocol B7471007 were identified for BIMO inspections. The sites were selected based upon previous BIMO inspection history, sponsor-reported adverse events, protocol deviations, and total number of subjects enrolled.

The inspections were conducted in accordance with FDA's Compliance Program (CP) 7348.811, Inspection Program for Clinical Investigators. 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

Protocol B7471007: *A Phase 3, Randomized, Double-blind, Trial to evaluate the safety and immunogenicity of a 20-valent pneumococcal conjugate vaccine in pneumococcal vaccine-naïve adults 18 years of age and older*

The sponsor reported a total of 3009 subjects enrolled under clinical study Protocol B7471007 at 54 sites in the United States and 7 in Sweden. A total of 2835 subjects completed the study. The inspected sites comprise about 2% of the total subjects enrolled under Protocol B7471007.

## BIMO INSPECTIONS SUMMARY

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

Study Site #	Firm Name	Location	Form 483 Issued	Inspectional Final Classification
1004	Kevin D. Cannon, M.D.	Wilmington, NC	No	NAI
1015	Shane Christensen, M.D.	Salt Lake City, UT	No	NAI
1028	Larkin T. Wadsworth, M.D.	St. Louis, MO	No	NAI

NAI = No Action Indicated

## INSPECTIONAL FINDINGS

The results from the inspections showed only a few minor issues which were resolved during the inspection.

## SPONSOR/MONITORING ISSUES

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

## 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, as well as if and when the information was 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 or [Malcolm.Nasirah@fda.hhs.gov](mailto:Malcolm.Nasirah@fda.hhs.gov).

Malcolm Nasirah, PharmD, MS, BCGP  
Consumer Safety Officer

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Reviewed: Cato 5/20/2021

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