

Our STN: BL 125731

**LATE-CYCLE
MEETING MEMORANDUM**

Wyeth Pharmaceuticals LLC
Attention: Patrick Thomas
500 Arcola Road
G4450
Collegeville, PA 19426

Dear Mr. Thomas:

Attached is a copy of the memorandum summarizing your April 7, 2021 Late-Cycle Meeting teleconference with CBER. This memorandum constitutes the official record of the meeting teleconference. If your understanding of the meeting teleconference outcomes differs from those expressed in this summary, it is your responsibility to communicate with CBER in writing as soon as possible.

Please include a reference to the appropriate Submission Tracking Number (STN) in future submissions related to the subject product.

If you have any questions, please contact Regulatory Project Manager Diana Oram, PhD at diana.oram@fda.hhs.gov.

Sincerely,

Doran Fink, MD, PhD
Deputy Director - Clinical
Division of Vaccines and Related Products
Applications
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research

Late-Cycle Meeting Summary

Meeting Date and Time: April 7, 2021 at 1:00 p.m. (EDT)
Meeting Location: Teleconference
Application Number: BLA STN 125731
Product Name: 20-valent Pneumococcal Conjugate Vaccine
Proposed Indications: Active immunization for the prevention of pneumonia and invasive disease caused by *S. pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F and 33F in adults 18 years of age and older.
Applicant Name: Wyeth Pharmaceuticals LLC
Meeting Chair: Christina Houck
Meeting Recorders: Diana Oram, Kamal Velmurugan, Juan Lacayo

FDA ATTENDEES

Ritu Agarwal, PhD	OCBQ/DBSQC
Marie Anderson, PhD	OCBQ/DBSQC
Phillip Blanc, MD, MPH	OBE/DE
Drusilla Burns, PhD	OVRR/DBPAP
Tatiana Claro da Silva, PhD	OVRR/DVRPA
Dennis Cato	OCBQ/DIS
Jon Daugherty, PhD	OVRR/DVRPA
Doran Fink, MD, PhD	OVRR/DVRPA
Ravi Goud, PhD	OBE/DE
Marion Gruber, PhD	OVRR
Kelsy Hoffman, PhD	OVRR/DVRPA
Christina Houck	OVRR/DVRPA
Hector Izurieta, MD	OVRR
James Erich Keller, PhD	OVRR/DBPAP
James Kenney, DSc	OCBQ/DBSQC
Hyesuk Kong, PhD	OCBQ/DBSQC
Philip Krause, MD	OVRR
Juan Lacayo, PhD	OVRR/DVRPA
Nicole Li	OCBQ/DMPQ
Loris McVittie, PhD	OVRR/DVRPA
Darya Melnyk, MSc	OCBQ/DBSQC
Tina Mongeau, MD, MPH	OVRR/DVRPA
Manette Niu, MD	OBE

Scott Norris	OVRP/DBPAP
LCDR Andrew O'Carroll, DVM	OVRP/DVRPA
Diana Oram, PhD	OVRP/DVRPA
Lisa Parsons, PhD	OVRP/DBPAP
Jay Slater, MD	OVRP/DBPAP
Muhammad Shahabuddin, PhD	OCBQ/DBSQC
Daphne Stewart	OVRP/DVRPA
Willie Vann, PhD	OVRP/DBPAP
Kamal Velmurugan, PhD	OVRP/DVRPA
Leslie Wagner	OVRP/DBPAP
Qun Wang, PhD	OVRP/DVRPA
Ruoxuan Xiang, PhD	OBE/DB
Lihan Yan, PhD	OBE/DB

APPLICANT ATTENDEES

Annaliesa Anderson, PhD	Vice President & Chief Scientific Officer for Bacterial Vaccines, Vaccines R&D
Katherine Arch-Douglas	Director, Global CMC, Vaccines
Barry Ballan, PMP	Senior Director, Vaccine Development Management
Alejandro Cane, MD	Vice President, Vaccine Medical & Scientific Affairs
Erica Chilson, PharmD	Senior Director, Vaccine Medical & Scientific Affairs
Jacqueline Dias	Senior Director, Global Regulatory Affairs
Stephanie Ferrari, MS	Senior Manager, Global CMC, Vaccines
Brad Gessner, MD	Vice President, Global Pneumococcal Vaccines, Vaccine Medical & Scientific Affairs
John Ginis	Director, Vaccines Clinical Research & Development
Heather Holloway, MD	Director, Safety & Risk Management
Rob Maroko, MD	Senior Director, Safety Disease Area Cluster Lead
Michael Pastorino	Clinical Study Team Lead, Clinical Operations
Yahong Peng, PhD	Senior Director, Vaccine Biostatistics
Ann Pennington, MS	Director, Statistical Programming & Analysis Group Lead
Cynthia Rohde, PhD	Senior Principal Scientist, Drug Safety R&D
Paul Rohlfing	Executive Director, Global CMC, Vaccines
Dan Scott, MD	Vice President, Vaccines Clinical Research & Development
Ingrid Scully, PhD	Senior Director, Clinical & Diagnostic Assay Development

Nancy Summerton
Patrick Thomas, MS
Wendy Watson, MD

Director, Pfizer Global Supply
Senior Director, Global Regulatory Affairs
Executive Director, Vaccines Clinical
Research & Development

BACKGROUND

BLA 125731 was submitted on October 8, 2021, for 20-valent Pneumococcal Conjugate Vaccine.

Proposed indications: Active immunization for the prevention of pneumonia and invasive disease caused by *S. pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F and 33F in adults 18 years of age and older.

PDUFA goal date: June 8, 2021

In preparation for this meeting, FDA issued the Late-Cycle Meeting Materials on March 25, 2021.

DISCUSSION

1. Discussion of Substantive Review Issues

At this time, CBER does not have any substantive review issues.

2. Information Requests

Two Information requests currently outstanding responses expected in the next week.

3. Risk Management Actions (e.g., REMS)

CBER has not identified any issues related to risk management; therefore, REMS is not needed.

4. Postmarketing Requirements/Postmarketing Commitments

CBER intends to communicate to the Applicant regarding Post Marketing Requirements by May 7, 2021.

5. Major Labeling Issues

The package insert, carton and container labels are being reviewed. CBER is working towards providing labeling comments before May 7, 2021.

6. Review Plans

CBER intends to take action on this application no later than June 8, 2021.

7. Applicant Questions

Applicant questions were addressed by email prior to the meeting. Applicant indicated that answers to their questions were clear and that they did not have any additional questions.

8. Wrap-up and Action Items

CBER intends to provide labeling comments before May 7, 2021.

CBER intends to communicate regarding Post Marketing Requirements by May 7, 2021.

CBER intends to take action on this application no later than June 8, 2021.

This application has not yet been fully reviewed by the signatory authorities, Division Directors and Review Committee Chair and therefore, this meeting did not address the final regulatory decision for the application.