



Our STN: BL 125770/0

**LATE-CYCLE
MEETING MEMORANDUM**

Pfizer Ireland Pharmaceuticals
Attention: Gosia Mineo

Pfizer Inc.
1 Pfizer Way
190/004/4405
Pearl River, NY 10965

Dear Ms. Mineo,

Attached is a copy of the memorandum summarizing your June 28, 2023, Late-Cycle teleconference with CBER. This memorandum constitutes the official record of the teleconference. If your understanding of the 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 Brynn Hollingsworth, PhD (Brynn.Hollingsworth@fda.hhs.gov), Moonsuk Choi, PhD (Moonsuk.Choi@fda.hhs.gov) or Maria Bagh, PhD (Maria.Bagh@fda.hhs.gov) via email or at (301) 796-2640.

Sincerely,

Loris D. McVittie, PhD
Deputy Director - Regulatory
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: June 28, 2023, 9:30 AM – 11:30 AM

Meeting Location: Teleconference

Application Number: BLA STN125770/0

Product Name: Meningococcal Groups A, B, C, Y, W Vaccine (PENBRAYA)

Proposed Indication: Active immunization of individuals 10 through 25 years of age to prevent invasive disease caused by *Neisseria meningitidis* groups A, B, C, W, and Y

Applicant Name: Pfizer Ireland Pharmaceuticals

Meeting Chair: CAPT Michael Smith, PhD

Meeting Recorders: Brynn Hollingsworth, PhD

Moonsuk Choi, PhD

Maria Bagh, PhD

FDA ATTENDEES

Maria Allende, MD	OVRD/DVIPA
Maria Bagh, PhD	OVRD/DVIPA
Margaret Bash, MD, PhD	OVRD/DBPAP
Rebecca Brady, PhD	OVRD/DBPAP
Michael Brony, PharmD	OCBQ/DCM
Drusilla Burns, PhD	OVRD/DBPAP
Dennis Cato	OCBQ/DIS
Moonsuk Choi, PhD, MS	OVRD/DVIPA
Anil Choudhary, PhD, MBA	OCBQ/DBSQC
Jim Crim	OCBQ/DMPQ
Tianjiao Dai, PhD	OBPV/DB
Maryna Eichelberger, PhD	OCBQ/DBSQC
Varsha Garnepudi, MS, RAC	OCBQ/DBSQC
Helen Gemignani	OVRD/DVIPA
Andrea Gray, PhD	ORO/DROP
Jared Greenleaf	OCBQ/DMPQ
Brynn Hollingsworth, PhD	OVRD/DVIPA
Harry Houghton, PhD	OBPV/DB
Lei Huang, PhD	OBPV/DB
David C. Kaslow, MD	CBER/OVRD
George Kastanis, MS	OCBQ/DBSQC
James (Erich) Keller, PhD	OVRD/DBPAP
Jennifer Kirk, PhD	OBPV/DB
Lucia Lee, MD	OVRD/DVIPA
Shiowjen Lee, PhD	OBPV/DB
Nicole Li	OCBQ/DMPQ

Tsai-Lien Lin, PhD	OBPV/DB
Lunhua Liu, PhD	OVRP/DBPAP
Loris McVittie, PhD	OVRP/DVRPA
Kathryn Matthias, PhD	OVRP/DBPAP
Narayan Nair, MD	OBPV/DPV
Cassandra Overking, MPH	OVRP/DVRPA
Tao Pan, PhD	OCBQ/DBSQC
Lisa Parsons, PhD	OVRP/DBPAP
Lori Peters, MS	OCBQ/DMPQ
Yen Phan, PhD	OCBQ/DBSQC
Douglas Pratt, MD, MPH	OVRP/DVRPA
Kirk Prutzman, PhD	OVRP/DVRPA
Michael Schmitt, PhD	OVRP/DBPAP
John Scott, PhD	OBPV/DB
Jay Slater, MD	OVRP/DBPAP
Michael Smith, PhD	OVRP/DVRPA
Daphne Stewart	OVRP/DVRPA
Elizabeth Sutkowski, PhD	OVRP/DVRPA
Xinyu Tang, PhD	OBPV/DB
Joseph Toerner, MD, MPH	OVRP/DVRPA
Nicole Trudel	OCBQ/DMPQ
Hsiaoling (Charlene) Wang, PhD	OCBQ/DBSQC
Willie Vann, PhD	OVRP/DBPAP
Jerry Weir, PhD	OVRP/DVP
Kerry Welsh, MD, PhD	OBPV/DPV

APPLICANT ATTENDEES

(b) (6)	Technical Portfolio Lead-Vaccines, Pfizer Global Supply
Kofi Asomaning, MD, PhD	Senior Director, Safety Surveillance Research
Phoebe Baldus, PhD	Senior Director, Biotherapeutics Pharmaceutical Sciences, Analytical Research and Development (R&D)
Paul Balmer, PhD	Vice President, Global Medical Affairs
Carmel Devlin	Vice President, Global Regulatory Sciences
Riddhi Desai	Senior Manager, PGS Co-dev Team Lead, Vaccines (non-mRNA)
Nathalie Dubois	Senior Director, Global Regulatory Sciences, Vaccines CMC
Eduardo Forleo, MD	Vice President, Vaccines Clinical R&D
Renu Garg, PhD, MPH	Associate Director, Safety Surveillance Research
(b) (6)	Senior Scientist, Biotherapeutics Pharmaceutical Sciences Analytical R&D
Wesley Harlow, MBA	PMP Associate Director, Vaccine Development Management (Program Director for Mn Franchise)

Joan Kwong	Director, Global Regulatory Sciences, Vaccines CMC
(b) (6)	Clinical Study Team Lead, Clinical Development and Operations
Jason D. Maguire, MD, MPH	Senior Director, Vaccines Clinical R&D
Matthew Marsden, PhD	Senior Director, Global Regulatory Sciences
Gosia Mineo	Director, Global Regulatory Sciences
(b) (6)	Associate Research Fellow, Biotherapeutics Pharmaceutical Sciences Analytical R&D
Beth Moughan	Director, Vaccines Clinical R&D
Ashlesh Murthy, MBBS, PhD	Director, Bacterial Vaccines and Technology
Paula Peyrani	Senior Director, Global Medical Affairs
Lynn Phelan, PhD	Executive Director, Early Bioprocess Development
Claire Roche	Director, Global Regulatory Sciences, Vaccines CMC
(b) (6)	Safety Risk Lead, Safety Surveillance & Risk Management

BACKGROUND

BLA 125770/0 was submitted on October 21, 2022, for Meningococcal Groups A, B, C, Y, W Vaccine (PENBRAYA).

Proposed indication: Active immunization of individuals 10 through 25 years of age to prevent invasive disease caused by *Neisseria meningitidis* groups A, B, C, W, and Y

PDUFA goal date: October 20, 2023

In preparation for this meeting, FDA issued the Late-Cycle Meeting Materials on June 14, 2023.

DISCUSSION

1. Discussion of Substantive Review Issues

a. **Biostatistical Issues Regarding the Chemistry, Manufacturing and Control (CMC) Information (under Module 3.2.P.5.3 Validation of Analytical Procedures):**

We reference the information request that was sent to you on June 12, 2023, with respect to the CMC Biostatistical issues regarding the study design and statistical analysis approach to your assay validation procedures, given the assay was developed at a non-routine testing lab. We have requested a response to

our information request by June 26, 2023. Time during the late cycle meeting will be reserved for further discussion of this issue.

Meeting Discussion:

Pfizer reiterated their commitment to providing additional assessments by July 27, 2023, as stated in their response to our information request of June 12, 2023 submitted in amendment 23 on June 26, 2023. CBER confirmed receipt of the amendment and looks forward to receiving the additional analyses in July.

b. Inspections:

The Agency is waiving all manufacturing facility inspections associated with your license application; however, if manufacturing concerns are identified or the compliance status is no longer deemed acceptable, the Agency reserves the right to perform a facility inspection during the course of the review period.

BIMO inspections are scheduled and/or ongoing. A final recommendation is pending at this time. However, if we learn of any issues from the outstanding BiMO inspections, the agenda will be modified accordingly.

Meeting Discussion:

This item was not discussed.

2. Discussion of Minor Review Issues

a. Pfizer's Revised Pediatric Plan:

In principle, your revised pediatric plan is acceptable. However, we would like to discuss the milestone dates regarding your planned Phase 2 and Phase 3 studies, Studies B1971067 and C3511005, respectively. Guidance will be communicated to Pfizer regarding Studies B1971067 and C3511005 under IND 17319.

Meeting Discussion:

CBER noted that in general we are in agreement with the approach proposed for the Phase 2 study, but plan to communicate specific comments regarding PENBRAYA and TRUMENBA studies via email under the INDs. Pfizer asked when the guidance is expected to be provided and CBER replied that it may be provided in August as we are bringing this product before PeRC on August 15, 2023.

b. Postmarketing Commitment of a Pregnancy Study:

The review team is requesting a postmarketing commitment (PMC) for a pregnancy study (an information request was sent to Pfizer regarding this study on June 6, 2023). We would like to discuss the feasibility of this study with you.

Meeting Discussion:

CBER confirmed receipt of the pregnancy study protocol synopsis submitted June 20, 2023 and noted review of the synopsis is still ongoing. Additional information will be requested via email as needed.

3. Outstanding Information Requests

- Information Request dated June 6, 2023, regarding a pregnancy study, with reference to Amendment 17, received May 25, 2023, in response to the Information Request sent May 10, 2023 (Response expected by June 20, 2023)
– A response to this information request was received on June 20, 2023 and is under review.
- Information Request dated June 6, 2023, regarding CMC comments pertaining to (b) (4) and stability data for MnB Bivalent (b) (4) Drug Product (DP) (Response expected by June 21, 2023)
– A response to this information request was received on June 21, 2023 and is under review.
- Information Request dated June 12, 2023, with respect to CMC Biostatistical issues regarding validation of analytical procedures (Response expected by June 26, 2023)
– A response to this information request was received on June 26, 2023 and is under review.

Meeting Discussion:

This item was not discussed.

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

There is no anticipation of a REMS) at this time.

Meeting Discussion:

This item was not discussed.

5. Postmarketing Requirements/Postmarketing Commitments

There will be a PREA PMR for an assessment in children 1 to less than 10 years of age.

We reference communications dated May 10 and June 6, 2023, regarding a request for a PMC for a pregnancy study.

You will be informed of any additional PMR(s) and PMC(s) by August 26, 2023, and September 21, 2023, respectively.

Meeting Discussion:

This item was not discussed.

6. Major Labeling Issues

The PENBRAYA package insert, and outer carton and container labels are currently under review. Comments and requests for revisions on proposed product labeling will be communicated by September 21, 2023.

Meeting Discussion:

This item was not discussed.

7. Review Plans

Reviews are expected to be completed on time. However, the final review depends upon the information received in upcoming submissions.

Meeting Discussion:

This item was not discussed.

8. Applicant Questions

Meeting Discussion:

Pfizer wished to further discuss the issue of the (b) (4) (b) (4) process, for which CBER had sent four information requests thus far. CBER confirmed receipt of responses to information requests regarding this process and the rationale behind it, while noting one more information request would be sent to Pfizer. Pfizer noted that they plan to submit to the BLA by the end of August a data package regarding (b) (4) of the batches of (b) (4) process (b) (4).

9. Wrap-up and Action Items

Meeting Discussion:

Pfizer was reminded that CBER will send the meeting minutes to Pfizer within 30 days.

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.