

**MID-CYCLE MEETING SUMMARY**

To:	The File
From:	Ramachandra Naik, Ph.D., RPM
Through:	Drusilla Burns, Ph.D., Chair
Meeting Date:	September 29, 2014
STN #:	125549/0
Submission Type:	Original BLA
Applicant:	Wyeth Pharmaceuticals, Inc.
Product:	Meningococcal Group B Vaccine
Meeting Chair:	Drusilla Burns
Meeting Recorders:	CDR Michael Smith, LCDR Theodore Garnett and Ramachandra Naik

**CBER/FDA ATTENDEES**

<b><u>Review Assignment</u></b>	<b><u>Committee Members</u></b>	<b><u>Attendance</u></b>	<b><u>Supervisors</u></b>	<b><u>Attendance</u></b>
Chair	Drusilla Burns, Ph.D.	✓	Jay Slater	
Lead Regulatory Project Manager	Michael Smith, Ph.D.	✓	Elizabeth Sutkowski	✓
Regulatory Project Manager	Theodore Garnett, Ph.D.	✓	Elizabeth Sutkowski	✓
Regulatory Project Manager	Ramachandra S. Naik, Ph.D.	✓	Elizabeth Sutkowski	✓
Clinical reviewer	Lucia Lee, M.D.	✓	Jeff Roberts	
Product, product test methodologies <sup>1</sup> , and DBPAP Regulatory Coordinator	Tina Roecklein, M.S.	✓	Jay Slater	
Bioassay (clinical serology and product test methodologies <sup>2</sup> )	Freyja Lynn, B.S.	✓	Jay Slater	
Bioassay (hSBA) consult <sup>3</sup>	Margaret Bash, M.D., M.P.H.	✓	Willie Van	
HPV assay reviewer	Haruhiko Murata, Ph.D.	✓	Keith Peden	
Product test methodologies <sup>4</sup> reviewer	Alfred Del-Grosso, Ph.D.	✓	Lokesh Bhattacharyya	
Product test methodologies <sup>5</sup> reviewer	Anil Choudhary, Ph.D.	✓	William McCormick	✓
Product test methodologies <sup>6</sup> reviewer	Hyesuk Kong, Ph.D.	✓	James Kenney	
Lot release and Regulatory Coordinator	Karen Campbell, M.S.	✓	William McCormick	✓
Coordination of lot release –	Cheryl Hulme, M.L.T.,		Joseph Quander III	

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DMPQ	A.S.C.P.			
Biostatistics reviewer	Barbara Krasnicka, Ph.D.	✓	Dale Horne	✓
Statistical Reviewer	Mridul Chowdhury, Ph.D.	✓	Dale Horne	✓
Statistical reviewer	Tsai-Lien Lin, Ph.D.	✓	Dale Horne	✓
Non-clinical/Toxicology reviewer	Steven Kunder, Ph.D.		Dave Green	✓
Facilities, CCIT <sup>7</sup> Reviewer	Nancy Waites, M.S.	✓	Carolyn Renshaw	✓
Epidemiology reviewer	Laura Polakowski, M.D., M.S.P.H.	✓	Wei Hua	✓
Bioresearch Monitoring Reviewer	Lillian Ortega, M.P.H.	✓	Patricia Holobaugh	
Advertising/Promotional Labeling	Michael Brony, Pharm.D.	✓	Lisa Stockbridge	
Regulatory Project Manager – DMPQ	Leigh Bernardino, R.N., B.S.N.	✓	James Crim	
Carton and container labeling	Daphne Stewart	✓	Laraine Henchal	✓
Electronic Integrity	David Schwab, M.S.I.S.		Laraine Henchal	✓

1 = Primary reviewer: Purity to include % purity, -----(b)(4)-----  
----- (DS and DP), ----(b)(4)---- (DS), -----(b)(4)-----  
----- (DS)

2 = Primary reviewer: -----(b)(4)----- (DS and DP), (b)(4) potency (DP)

3 = Will not be providing a review memo as a consultant on this BLA

4 = Primary reviewer : Appearance -(b)(4)- DP), pH ((b)(4) DP), PS80 -----  
----- (b)(4)-----  
DP), -----(b)(4)----- (DS), ----(b)(4)---- (DP), -----(b)(4)---  
----- (DP), Volume of injection (DP), Aluminum (DP), ----(b)(4)----  
(DP)

Supporting reviewer: Purity (DP -(b)(4)-)

5 = Primary reviewer: Identity -----(b)(4)----- DP)

Supporting reviewer: -----(b)(4)----- (DS and DP), ----(b)(4)---- (DS),  
----- (b)(4)----- (DP)

6 = Primary reviewer: Bioburden (b)(4), Endotoxin ((b)(4) DP), Sterility (DP)

7 = Primary reviewer: Container closure integrity testing (DP)

**Other Attendees**

Mark Schwartz

John Eltermann

Philip Krause

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Anuja Rastogi  
Douglas Pratt  
Karen Farizo

Laurie Norwood  
Bhanu Kannan  
Loris McVittie

Maureen Hess

## **1.0 BACKGROUND**

STN 125549/0 was submitted by Wyeth Pharmaceuticals, Inc. (a subsidiary of Pfizer, Inc.) on June 16, 2014 and received by CBER on June 16, 2014. The proposed BLA indication is "Active immunization to prevent invasive meningococcal disease caused by *N. meningitidis* serogroup B in individuals aged 10 through 25 years".

## **2.0 PURPOSE**

To discuss the progress of the review, identify and present any remaining issues, plan the remainder of the review including dates for further deliverables and interactions, obtain supervisory feedback, and agree upon the material to be communicated in the Mid-cycle communication.

### **2.1 Meeting Agenda:**

- Milestones and internal/projected targets dates
- Status of IR comments sent to the sponsor and review of amendments received
- Reviewer updates on primary review assignments
- Action Items

## **3.0 DISCUSSION**

### **3.1 Chair/Lead Regulatory Project Manager Updates**

The Chair informed the review team of the following deadlines regarding review memos:

- Draft review due to Supervisor on October 3, 2014 (with copy sent to Chair and Lead RPM)
- Finalized review signed by supervisor due on October 10, 2014

### **3.2 Reviewer Updates on Primary Review Assignments**

Each reviewer (designee) gave a brief update on the status of their review of the BLA. No major issues were reported.

## **4.0 ACTION ITEMS**

Review comments on carton and container labeling will be sent to the applicant on or before October 3, 2014.

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