

**MEETING AGENDA**

Date and Time:	August 29, 2011 1:00 pm – 2:00 pm
Location:	WOC2 – Room 2201
Call-In Information:	Toll-Free Number: ---b(4)----- Passcode: ---b(4)-----
STN #:	125363/0
Sponsor:	GlaxoSmithKline Biologicals
Product:	Menhibrix, Meningococcal Groups C, and Y and Haemophilus b Tetanus Toxoid Conjugate Vaccine

CBER/FDA Invitees**COMMITTEE MEMBERS:**

Review Assignment	Committee Member	Supervisor	Attended
Chair	Joseph Temenak	Elizabeth Sutkowski	✓
RPM	David Staten	Elizabeth Sutkowski	✓
RPM	Kirk Prutzman	Elizabeth Sutkowski	✓
Clinical Reviewer	Meghan Ferris	Lucia Lee	✓
Product CMC/Serology	Mustafa Akkoyunlu	Willie Vann	✓
Product CMC	Willie Vann	Jay Slater	✓
Product CMC	Daron Freedberg	Willie Vann	✓
Product CMC	Drusilla L Burns	Jay Slater	✓
Product CMC	Annisa Cheung		
Product CMC	Freyja Lynn		✓
Product CMC	James E Keller	Drusilla Burns	✓
Product CMC	Majid Laassri	Konstantin Chumakov	
Product CMC	Steven A Rubin	Konstantin Chumakov	
Product CMC	Michael Schmitt		
Product CMC	Shuang Tang	Philip Krause	
Product CMC	Iryna Zubkova		
Toxicology	Steven C Kunder	David Green	
Product CMC	Tina Roecklein	Jay Slater	✓
Facilities/DMPQ	Sean Byrd	Carolyn Renshaw	
Advertising/ Promotional Labeling	Maryann Gallagher	Lisa Stockbridge	✓
Clinical Statistical Reviewer	Barbara Krasnicka	Dale Horne	✓
Assays Statistical Reviewer	Tsai-Lien Lin	Dale Horne	✓
Epidemiology	Manette Niu	Thomas Buttolph	
DPQ/Lot Testing Plan	Rajesh Gupta	Bill McCormick	✓
DPQ/Lot Testing Plan	Karen Campbell	Bill McCormick	✓

Review Assignment	Committee Member	Supervisor	Attended
Lot Release	Joe Quander	Jay Elterman	
BiMo	Soloman Yimam	Patricia Holobaugh	✓
Electronic Integrity Review	David Schwab	Laraine Henchal	

OTHER ATTENDEES:

Douglas Pratt
Elizabeth Sutkowski
Theresa Finn
Marion Gruber

1.0 PURPOSE

On April 15, 2011, GlaxoSmithKline Biologicals On (GSK) submitted a complete response to the CR letter and resubmitted a new biologics license application (BLA) for review to support the licensure of MenHibrix for active immunization of infants and toddlers 6 weeks through 15 months of age for the prevention of invasive diseases caused by *Haemophilus influenzae* type b and *Neisseria meningitidis* serogroups C and Y. At the August 8, 2011 meeting, the review team provided justification for why this submission cannot be approved at this time and IOD concurred with this decision. The purpose of this August 29, 2011 committee meeting is to discuss our milestones as we proceed to the CR Letter. We will discuss which items will be included in the CR Letter and which items will included in an Information Request Letter. We will also discuss review progress, upcoming review milestones and any issues which may impact the review process or the approval of the BLA.

2.0 BACKGROUND

Original BLA STN #125363 (eCTD Sequence #0000) was submitted by GlaxoSmithKline Biologicals on April 13, 2011 and received by CBER on April 13, 2011. The proposed indication is for active immunization of infants and toddlers 6 weeks through 15 months of age for the prevention of invasive diseases caused by *Haemophilus influenzae* type b and *Neisseria meningitidis* serogroups C and Y. On June 11, 2011 CBER issued a Complete Response Letter identify 88 separate deficiency items. On April 15, 2011, GSK submitted a complete response to the CR letter and resubmitted this BLA.

2.1 Milestones:

Milestone	Projected Date
▪ Application Received	April 15, 2011
▪ Committee Assignment	May 2, 2011
▪ 1st Committee Meeting	May 9, 2011
▪ Mid-Cycle Review Meeting	July 11, 2011
▪ 1st draft reviews	July 14, 2011
▪ 2 nd draft reviews	August 13, 2011
▪ Final Reviews (Signed/Uploaded)	August 28, 2011 (Sunday)
▪ Present to PeRC	August 31, 2011
▪ PMC to FDAAA SWG	August 31, 2011
▪ Labeling Target	September 28, 2011 (Sunday)
▪ PMC Study Target	September 28, 2011 (Sunday)
▪ First Action Due	October 15, 2011 (Saturday)

2.2 Meetings

First Committee Meeting:	May 9, 2011
Filing Meeting:	May 9, 2011
Monthly Team Meetings:	June 6, 2011 August 8, 2011 August 29, 2011 October 3, 2011
Mid-Cycle Review Meeting:	July 11, 2011
PeRC:	August 31, 2011
VRBPAC:	Not going to VRBPAC
SWG:	Not Scheduled
Labeling Meetings:	Not Scheduled

3.0 DISCUSSION TOPICS: STATUS AND ISSUES

3.1 CR/IR Issues – Updates on the CR Letter issues vs. IR Letter issues

The review management team (Kirk, Dave, and Joe) updated the review team and IOD as to the current status of the CR Letter Assignments spreadsheet.

3.2 The following timelines were proposed for issuing the CR Letter and the IR Letter

3.2.1 Proposed Timelines for the CR Letter

- A. Letter ready CR Items to Kirk, Dave, and Joe by **September 30, 2011**
- B. Final Letter to be sent to sponsor on October 14, 2011

3.2.2 Proposed Timelines for the IR Letter

- A. Letter ready IR Items to Kirk, Dave, and Joe by **September 23, 2011**
- B. Final Letter to be sent to sponsor on October 7, 2011

Note: We are trying to group all information requests into this request. This includes items that may have arisen in the reviews as well as previous CR Items that have not been completely addressed.

3.3 Team Reports/Review Status Updates

3.3.1 Clinical

Meghan Ferris reported that clinical had no items for the CR Letter or the IR Letter. The clinical review was waiting final sign-off from management.

3.3.2 Statistical

Barbara Krasnicka reported that she had no items for the CR Letter or the IR Letter. However, she indicated that she had some of the same issues with her review that Tsai-Lien will be indicating in her CR Letter comments. The clinical statistical review was complete and awaiting management sign-off.

Tsai Lien Lin reported that CR Letter Items 1 and 3 were still issues and will be in the second CR Letter. She indicated that GSK needed to submit data for internal controls for their hSBA assays. Tina Roecklein indicated that the product reviewers had similar issues and that they will discuss this together to generate the CR Letter items together. The assay statistical review was completed and waiting for management signoff.

3.3.3 Product

Mustafa Akkoyunlu reported that the MenY hSBA assay remained a CR issue. His review was complete and waiting for Willie Vann to sign off. Deron Freedburg reported that the free polysaccharide issues have been adequately addressed and that his review was complete and waiting for Willie Vann to sign off. Tina Roecklein reported that she is compiling all of the CMC/Product CR comments and IR comments. She reported that she had ~18 CR comments and 1-2 IR Comments. Tina planned to finalize the CR and IR items in the following week and send them to Kirk, Dave and Joe. Rajesh Gupta reported that his review was complete. DMPQ had no CR items but had 5 IR items. They were included in his review.

3.4 IOD DISCUSSIONS

Marion Gruber discussed that the proposed timeline for the CR and IR letters were too far in the future. Since the reviews were mostly complete and the CR Letter items were also mostly complete, she suggested sending out the CR Letter by the end of September. Marion also indicated that GSK should be notified that a CR Letter was being issued in early September. It was also discussed that that it might be better to address the IR Letter issues by an email request. Depending on the nature of the IR items they may possibly be incorporated into the CR Letter. The review team agreed and indicated that this timeline was possible.

Meeting Ended