

Review Committee Assignment, July 25, 2011 - MenHibrix

Date: July 25, 2011

To: 125363/12 File

Review Committee

From: Kirk Prutzman, Ph.D.

Thru: Joseph Temenak, Ph.D. Chair, MenHibrix Review Committee Assignment Memo

Subject: Addition of Lucia Lee, M.D. to Review Committee Assignment

Lucia Lee, M.D. has been assigned to GSK's CR response for MenHibrix (Meningococcal Groups C and Y and Haemophilus b Tetanus Toxoid Conjugate Vaccine) as a Clinical Reviewer.

The action due date for this application is **October 15, 2011**

Review Assignment	Committee Member	Supervisor
Chair	Joseph Temenak	Elizabeth
Sutkowski RPM	David Staten	Elizabeth
Sutkowski RPM	Kirk Prutzman	Elizabeth
Sutkowski Clinical Reviewer	Meghan Ferris	Lucia Lee
Sutkowski Clinical Reviewer	Lucia Lee	Douglas Pratt
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	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 Kransnicka	Dale Horne
Assays Statistical Reviewer	Tsai-Lien Lin	Dale Horne

Epidemiology
DPQ/Lot Testing Plan
DPQ/Lot Testing Plan
Lot Release
BiMo
Holobaugh
Electronic Integrity Review

Manette Niu
Rajesh Gupta
Karen Campbell
Joe Quander
Soloman Yimam

David Schwab

Thomas Buttolph
Bill McCormick
Bill McCormick
Jay Elterman
Patricia

Laraine Henchal