

Committee Assignment, September 9, 2009 - MenHibrix

Date: 9 September 2009
To: Review Committee, STN 125363/0 (Revised)
From: Jason Humbert
Thru: Joseph Temenak, Ph.D.
Chair, MenHibrix Review Committee
Subject: Committee Assignment, MenHibrix BLA STN 125363/0

The following committee has been assigned to GSK's electronic BLA for MenHibrix™ [Meningococcal Groups C and Y and Haemophilus b Tetanus Toxoid Conjugate Vaccine]

The action due date for this application is **June 12, 2010**.

Chair Joseph Temenak, Ph.D.

Committee Members

Clinical Reviewer/Labeling	Meghan Ferris, M.D.
Product CMC/Serology	Mustafa Akkoyunlu, M.D. Ph.D,
Product CMC	Willie Vann, Ph.D.
Product CMC	Daron Freedberg, Ph.D
Product CMC	Milan Blake, Ph.D.
Product/CMC	Tina Roecklein, MS
Product/CMC	James (Erich) Keller, Ph.D.
Product/CMC	Michael Schmitt, Ph.D.
Facilities/DMPQ	Joseph George
Facilities/DMPQ	Sean Byrd
Advertising/ Promotional Labeling	Maryann Gallagher
Clinical Statistical Reviewer	Barbara Krasnicka, Ph.D.
Assays Statistical Reviewer	Tsai-Lien Lin, Ph.D.
Epidemiology	David Menschik, M.D., MPH
DPQ/Lot Testing Plan	Rajesh Gupta, Ph.D.
DPQ/Lot Testing Plan	Karen Campbell
Lot Release	Joe Quander III
BiMo	Robert Wesley
Electronic Integrity Reviewer	David Schwab, MSIS
RPMs/RC	
DVRPA Regulatory Project Manager	Jason Humbert

DVRPA Regulatory Project Manager
DBPAP Regulatory Coordinator

David Staten, MPH
Jennifer Bridgewater, MPH

Any revisions to the review committee will be sent out via email.

A review schedule with timelines and due dates will be issued within the next few days. This is an electronic submission. The electronic link to the eBLA is attached below. Please access the file using the link below. If the link does not work, you may also access the BLA directly through the EDR. If you have any difficulties accessing the submission please contact the ERIC help desk.

Thanks,
Jason

The link below should open the application in GS Review.

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