

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
Product CMC/Serology
Product CMC
Product CMC
Product CMC
Product/CMC
Product/CMC
Product/CMC
Facilities/DMPQ
Facilities/DMPQ
Advertising/ Promotional Labeling
Clinical Statistical Reviewer
Assays Statistical Reviewer
Epidemiology
DPQ/Lot Testing Plan
DPQ/Lot Testing Plan
Lot Release
BiMo
Electronic Integrity Reviewer
RPMs/RC
DVRPA Regulatory Project Manager

Meghan Ferris, M.D.
Mustafa Akkoyunlu, M.D. Ph.D,
Willie Vann, Ph.D.
Daron Freedberg, Ph.D
Milan Blake, Ph.D.
Tina Roecklein, MS
James (Erich) Keller, Ph.D.
Michael Schmitt, Ph.D.
Joseph George
Sean Byrd
Maryann Gallagher
Barbara Krasnicka, Ph.D.
Tsai-Lien Lin, Ph.D.
David Menschik, M.D., MPH
Rajesh Gupta, Ph.D.
Karen Campbell
Joe Quander III
Robert Wesley
David Schwab, MSIS
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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