

# Monthly Meeting Summary, October 13, 2009 - MenHibrix

## MenHibrix

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Monthly Meeting Summary – October

Date: October 13, 2009

As required by OVRP, the review team for MenHibrix met via e-mail to present review issues to the Chair and indicate to the BLA RPMs whether any of these issues require communication to GSK.

## Members Present

Chair

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

Epidemiology

DPQ/Lot Testing Plan

DPQ/Lot Testing Plan

Lot Release

BiMo

DVRPA Regulatory Project Manager

DVRPA Regulatory Project Manager

DBPAP Regulatory Coordinator

Joseph Temenak, Ph.D.

Meghan Ferris, M.D.

Mustafa Akkoyunlu, M.D. Ph.D,

Willie Vann, Ph.D.

Daron Freedberg, Ph.D

Tina Roecklein, MS

Milan Blake, Ph.D.

James E. 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

David Martin, M.D.

Rajesh Gupta, Ph.D.

Karen Campbell

Joe Quander III

Robert Wesley

David Staten, MPH

Jason Humbert

Jennifer Bridgewater, MPH

## Discussion:

1. The Clinical Reviewer has identified issues to be included in an Information Request letter. These items will be forthcoming.
2. APLB is currently reviewing the proposed proprietary name MenHibrix and the product labeling.

3. The main outstanding issue thus far from an epidemiological standpoint is that they did not submit a draft synopsis or protocol for a phase 4 study which was requested at the pre-BLA stage. The epidemiology reviewers are working on what they would like to see in such a study and anticipate generating some comments that will need internal (DE/VSB) concurrence before forwarding to others on the BLA committee and ultimately conveying to the sponsor. GSK has indicated that they would like to discuss the topic with CBER, but that strategy will be to formulate our position first and convey comments in advance of a possible teleconference.
4. No other issues were presented. The committee will meet again in November.