

Committee Filing Meeting, September 21, 2009 - MenHibrix

Date: September 21, 2009

Milestones:

Application Received:	August 12, 2009
Committee Assignment	August 25, 2009
1st Committee Meeting	September 8, 2009
Filing Meeting	September 25, 2009 (via e-mail)
Filing Action/Deficiencies Identified	October 11, 2009
Action Due Date:	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	David Staten, MPH
DBPAP Regulatory Coordinator	Jennifer Bridgewater, MPH

Summary: An e-mail was sent to review committee members asking whether the BLA may be filed and whether any deficiencies have been identified that should be included in the filing notification letter. The unanimous response from the committee was that the BLA should be filed. The clinical reviewer indicated that several deficiencies have been identified and those letter-ready comments will be made available before the filing notification letter is drafted.

No other issues were raised. A filing notification letter will be issued on or before October 11, 2009. A mid-cycle meeting has been scheduled for January 12, 2010.