

First Committee Meeting, September 8, 2009 - MenHibrix

MenHibrix – STN 125363/0
First Committee Meeting
September 8, 2009

Agenda:

1. Review milestones
2. Discuss review assignments
3. Discuss review strategies

Milestones:

Application Received:	August 12, 2009
Committee Assignment	August 25, 2009
1 st 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

Committee Assigned:

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
BiMo
Electronic Integrity Reviewer

Joe Quander III
Robert Wesley
David Schwab, MSIS

RPMs/RC

DVRPA Regulatory Project Manager Jason Humbert
DVRPA Regulatory Project Manager David Staten, MPH
DBPAP Regulatory Coordinator Jennifer Bridgewater, MPH

Discussion Items:

After an account of participants in the meeting was conducted, Dr. Joseph Temenak introduced himself to the committee and provided an overview of the BLA and the associated milestones and timelines.

Regarding Bioresearch Monitoring (BiMo), the clinical reviewer will contact BiMo to determine which sites for the pivotal U.S. study (Hib-MenCY-TT-009/010) will be investigated. Additionally, sites from study Hib-MenCY-TT-007/008 conducted in Australia may be investigated as this study provides data for administration of MenHibrix with MMR/Varicella vaccines. The clinical review team will provide 3 sites for possible inspection in the U.S. and notify BiMo if any of the data in the Australian study which may warrant an inspection. BiMo stated that they need at least a 60 (preferably a 90) day notice for any foreign inspections. As a early notice, the product review division stated that the site in the Netherlands where the 'C' and 'Y' bactericidal assays are conducted will be of interest with regard to BiMo inspection. The product division will recommend the assay sites to BiMo and will send one reviewer to accompany BiMo on the inspection.

Regarding the pre-licensure inspection, DMPQ stated that the tetanus toxoid purification occurs in November at a facility ----(b)(4)----- that has not been previously inspected. DMPQ inquired as to who will accompany the facility inspectors. The product division will discuss internally.

The topic of VRBPAC was discussed and whether this BLA will need to go before the Advisory Committee. Because of the indication and the dosing schedule of 2, 4, 6 and 12-15 months of age, this application may need to go to VRBPAC.

A meeting with PeRC will be scheduled after the application is filed.

DPQ stated that the lot release protocols will be discussed after the reviews are drafted (after mid-cycle). DBPAP will figure out the critical pieces and be in touch with DPQ through the coordination of the RPMs regarding lot testing.

The Product Release Branch (PRB) will need to be included on communications regarding the request for samples and reagents from GSK.

The proprietary name review will be conducted initially in September/early October and then again prior to approval. APLB is aware of the proposed proprietary name and will communicate to the Chair, clinical reviewer and the RPMs the recommendation regarding the proprietary name.

Reviewers were reminded to be clear about what information was reviewed in their memos. Reviewers were also reminded that any additional information provided in response to a telecon or e-mail should be referenced in the review memo.

Dr. Temenak advised everyone to be aware of the filing decision e-mail coming soon. The meeting concluded.