

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

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|-----------------------------------|-------------------------------|
| Chair | Joseph Temenak, Ph.D. |
| 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 | Tina Roecklein, MS |
| Product/CMC | Milan Blake, Ph.D. |
| Product/CMC | James E. 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 |
| Epidemiology | David Martin, M.D. |
| DPQ/Lot Testing Plan | Rajesh Gupta, Ph.D. |
| DPQ/Lot Testing Plan | Karen Campbell |
| Lot Release | Joe Quander III |
| BiMo | Robert Wesley |
| DVRPA Regulatory Project Manager | David Staten, MPH |
| DVRPA Regulatory Project Manager | Jason Humbert |
| DBPAP Regulatory Coordinator | 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.