Review Committee Meeting Summary, January 20, 2010 - Menveo

BLA 125300_0
Novartis ACYW-135 Mening Vaccine

January Review Committee Meeting Summary

Date	Time	Location	US Call in	Password	International Call in - Toll
Wednesday, January 20, 2010	3:00 – 4:00 PM EST	WOC1 200S	-------b(4)-------	Participant Passcode -b(4)------- Leader pass code --b(4)---	---b(4)---------- ---

1. Attendance –

Al-Humadi, Nabil,Tox
Bash, Margaret - Clin
Blake, Milan- hSBA Product
Burns, Drusilla -Assay Validation
Campbell, Karen- DPQ
Fiore, Cara - RPM
Freedberg, Daron- Product
George, Joseph- Facilities
Gupta, Rajesh- DPQ
Krasnicka, Barbara- Stat
Lee, Robert- Product
Miller, Catherine- APLB
Roecklein, Tina- Product Coord
Senthil, Geetha- OBE/DE Rep
Sun, Wellington- Director, DVRPA
Vann, Willie- CHAIR
White, Janet- BIMO
Valenti, Elizabeth- RPM

2. Review of latest submission – if you have material in the latest submission that you are responsible for reviewing, please insure it is covered in your review. All reviews to be finished (except label) by Wednesday January 26, 2010 so the action package can be routed Friday, January 29, 2010.
3. Resolution of problems with clinical and statistical reviews
4. Team Reports and Review Status

a. Clinical and PI – The clinical reviewer points out that that the statistical reviewer expressed her concern about the neurologic events and suicide rates in the Menveo arm, however, there is not an imbalance in these events and it will be clarified in the clinical review. Novartis will have to perform a large safety study as part of a post

marketing commitment, which will monitor these events. Regarding the immunologic data in the P18 study, the data suggests that concomitant administration with TdaP and one dose of Gardasil does not interfere with the Menveo response. But, there may be interference with acellular pertussis antigens filamentous hemagglutinin and pertactin when TdaP is administered concomitantly with Menveo and Gardasil. CBER has asked Novartis to add another post marketing study to evaluate this. The data is inadequate to determine the responses of the other vaccines.
We have had one cycle with the package insert with the sponsor and will continue to work on it.

b. Statistical - done
c. BIMO - done
d. DPQ – The DPQ director is reviewing this review. The Lot Release Protocol has been reorganized and was sent to Joe Quander for final review. There are problems with in-support testing, but these can/will be worked out with Novartis post-license.
e. CMC– Robert Lee. Review completed
f. CMC – Daron Freedberg. Review not completed/
g. DMPQ – Joe George. Will upload and provide the inspection tab by Wednesday the 28th.
h. Labeling – APLB review done
i. Toxicology - done
j. Reproductive Toxicology - done
k. Assay Validation – done (except hSBA). hSBA assay – Dr. Baylor will have to review Dr. Blake's review. Dr. Blake should send it to him immediately.
l. OBE/PMC – PBE/DE has information in the newest amendment that will have to be reviewed.