Review Committee Meeting Summary, December 16, 2009 - Menveo

- BLA 125300_0
  Novartis ACYW-135 Mening Vaccine

December Review Committee Meeting Summary

Date	Time	Location	US Call in	Password	International Call in - Toll
Wednesday, December 16, 2009	3:00 – 4:00 EST PM	WOC1 200S	--b(4)----------	Participant Passcode --b(4)----- Leader pass code - b(4)---	--b(4)----------

Attendees:
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
Vann, Willie- CHAIR
Martin, David- OBE
Valenti, Elizabeth- RPM
White, Janet- BIMO

1. Team Reports
   a. Clinical – Assessment, conclusions and executive summary will be competed shortly. They have some severe local reactions that may be considered safety issues for PMCs.
   b. Statistical - B. Krasnicka – review will be completed by Christmas.
   c. BIMO - done
   d. DPQ – It appears that the testing that needs to be performed for launch material will not be completed in time. January 15, 2010 is target for reviews to be completed. The release protocol template needs to be trimmed. It is 62 pages long. We should set up a telecom.
   e. CMC– Novartis has not yet replied to the Information Request (Formaldehyde ---b(4)---------- testing). They should be reminded.
   f. DMPQ

g. Labeling – APLB review done. Will consult with OVRR/Theresa Finn on wording for formaldehyde in the label.
h. Toxicology - done
i. Reproductive Toxicology - done
j. Assay Validation – done (except hSBA)
k. OBE/PMC – There are two PMCs plus a pregnancy registry that will be in a part of the approval package. OBE has 5 comments on the proposed study that needs to be worked out with the sponsor and CBER needs a response by the first week of January, mid week. 1) Novartis cut down their events of interest (EOI). Please provide a rationale. 2) Adjudicators ICD9 codes. 3) Novartis has written that the enrollees must have 6 months of stability for health conditions, which is a selection bias for a healthy populations 4) the study is underpowered to detect rare events and the sponsor needs to reword this section, 5) the sponsor does not clearly define what an unrelated event is. Safety working group meeting is January 14th, 2010. This must be worked out by the beginning of that week so this wording of the PMCs can be included in the approval letter.
l. Carton container packaging review – We will follow-up with comments via a telecon to the sponsor.

2. Action Items

Telecons needed to be set up:

- CMC - testing (Vann, Fredberg)
- Lot Release Protocol (DPQ)
- Carton Container (Vann, Valenti and Fiore)