Review Committee Meeting Summary, April 8, 2009 - Menveo

BLA 125300_0
Novartis ACYW-135 Mening Vaccine

April Review Committee Meeting Summary

Date	Time	Location	US Call in	Password	International Call in - Toll
Wednesday April 8, 2009	3:00 – 4:00 EST PM	RM 1st Floor WOC 1 WOC- 1 Building	--b(4)---------- --	Participant Passcode -b(4)----- Leader pass code -b(4)---	---b(4)---------- ---

1. Attendees
   Al-Humadi, Nabil
   Bash, Margaret
   Blake, Milan
   Burns, Drusilla
   Campbell, Karen
   deVore, Nikki
   Fiore, Cara
   George, Joe
   Gruber, Marion
   Gupta, Rajesh
   Lee, Robert
   Meysick, Karen
   Miller, Cathy
   Roecklein, Tina
   Trudell, Nicole
   Valenti, Elizabeth
   Vann, Willie
   White, Janet

2. Running list of Amendments
   a. optimizing CRM 197 innocula (0.1)
   b. Extractables and Leachables (0.2)
   c. Partial DI response (0.3)
   d. Partial DI response and additional info (0.4)
   e. Response to IRs. (0.5)
   f. HPV V59P18 (0.6)
   g. Pharmacovigilance Response
   h. Correction to LIMS and updated product list

3. CR Issues (reviews that have CR issues have **letter ready** CR comments by April 28th).

If there are no CR issues, please upload your review to the EDR. By May 15th, the letter will be in final draft form and reviewed by the Directors. All reviews should be in final draft form. All reviews that have CR issues will go to the Office Director.

4. Team Reports
   a. Clinical – *the complete review will take a little longer. CR comments will be ready by the end of next week. The PeRC committee will meet on April 22nd for this product.*
   b. Statistical – *There will be CR issues*.
   c. BIMO – *Only two EIRs have been received, but all four inspections have been completed. No CR issues seen. The two outstanding inspections have 483 issues (Drs. Baxter and Block). Both sites had problems maintaining accurate case histories. There are concerns about this and BIMO will obtain the EIR to determine the extent of the problems.*
   d. DPQ - is *working on the lot release protocol. They will try to get that in by the end of the month. DPQ has not received the samples for testing and has not been in correspondence with the company on technical transfer of SOPs and necessary assays to complete the sample testing. This should be initiated ASAP. The product reviewers will also meet to discuss and revise the CR issues.*
   e. CMC–*R. Lee review Completed*
   f. CMC – D. Freedberg. *Not available.*
   g. DMPQ – *The sponsor is required to address everything on the 483, however there has not been a response to the PAI (483 items). There are new questions regarding the comparability protocols that will be discussed with OCBQ management.*
   h. Labeling – *Review completed by APLB. The label will be reviewed by DVRPA as well for CFR compliance.*
   i. Toxicology – *Review completed.*
   j. Reproductive Toxicology - *review completed and is in final sign off stages.*
   k. Assay Validation (DTaP finished) – *hSBA validation concerns will be addressed in the IND.*
   l. OBE/PMC – *Review completed. There are concerns on the pharmacovigilance plan and this will have to be addressed with the sponsor.*

5. Upcoming events

   1. PeRC/PREA –April 22, 2009

6. Documents/Communications – Reviews, memos, telecons, emails, meetings summaries, etc.
   a. All deadlines include uploading **s**igned, certified pdf with attached Word doc into EDR. If you have problems, please email david.schwab@fda.hhs.gov and cc me (cara.fiore@fda.hhs.gov).
   b. Send all original reviews, telecons, memos, etc to DVRPA (Cara Fiore)

c. Communication with sponsor – please capture all communications with the sponsor and email them to the regulatory coordinators and Chair. They will have to be listed on the documentation review spread sheet for the Division Director.
d. esubmission link: \\cbsap58\m\eCTD_Submissions\STN125300\125300.enx

Committee assignments, Roles and Responsibilities (SOPP 8401)

Al-Humadi, Nabil- Tox
Austin-Hansberry, Lori- OBE - reg coor
Bash, Margaret- Clin
Blake, Milan- hSBA Product
Burns, Drusilla- Assay Validation
Campbell, Karen- DPQ
Devore, Nicole- Prod coord trainee
Fiore, Cara- RPM
Freedberg, Daron- Product
George, Joseph- Facilities
Green, Dave Tox Chief (cc)
Gruber, Marion- Repro tox
Krasnicka, Barbara- Stat
Lee, Martha- Stat – assay
Lee, Robert- Product
McVittie, Loris- Dep Dir DVRPA (cc)
Meysick, Karen- Assay Validation
Miller, Catherine- APLB
Pratt, Doug- Clin Chief (cc)
Richman, Paul- Branch Chief (cc)
Roecklein, Tina- Product Coord
Schraeger, Lewis- Clin Chief, (cc)
Schwab, David- Elect. Integ
Sutkowski, Liz (Branch Chief)
Sun, Div Dir DVRPA (cc)
Trudel, Nicole- Facilities
Vann, Willie- CHAIR
White, Janet- BIMO
Wise, Robert- OBE
Menschik, David- PMS
Valenti, Elizabeth- Back up RPM

7. Major Due Dates are on Table below

Milestones	**Date**
STN Assignment	11Sept08
Committee Assignment	11Sept08
1st Committee Meeting	17Sept08
VRBPAC Determination	12Oct08
Filing Meeting	>13Oct08
PeRC – schedule pres.	27Oct08
Filing Action	>28Oct08
Deficiencies identified	>11Nov08
Draft Reviews Due/Mid Cycle review	**25Jan09**
PREA determination	25Jan08
Final Reviews Due	**26Mar09**
PMC to FDAAA Safety WG	06May08
Package to Branch Chief	27May09
Final Action Due Date	**29Jun09**
Action Package Posting	**01Jul09**
Monthly Meetings (Team report)	Every Month
IOD Monthly Update	Every Month

8. Next Meetings –
   a. May 6, 2009 (Wednesday), 3:00 – 4:00

9. Questions/Comments/Concerns?
   a. Please continue to include Cara and Betsy on emails.

10. Action Items
    a. Follow up on statistical issues (Chair/RPM)
    b. Follow up on the outstanding EIRs (BIMO/Clinical)
    c. Follow up on the sample testing plan and technical transfer of necessary assays (DPQ)