October Monthly Meeting Summary - Menveo

- BLA 125300_0
  Novartis ACYW-135 Mening Vaccine
  W. Vann, Chair
  C. Fiore, Primary Reviewer

October Monthly Meeting Summary *(comments in itals)*

1. Introductions

The following people attended either by phone or in person:

Al-Humadi, Nabil
Austin-Hansberry
Bash, Margaret
Blake, Milan
Burns, Drusilla
Campbell, Karen
deVore, Nikki
Fiore, Cara
George, Joe
Krasnicka, Barbara
Lee, Martha
Lee, Robert
Meysick, Karen
Trudell, Nicole
Vann, Willie
White, Janet
Wise, Robert
Menschik, David

We have two more reviewers – Milan Blake is now reviewing the hSBA assays and David Menschik is reviewing PMS information.

2. Filing letter is in final review (done). T*he filing letter is in final sign off stages.*
3. Major Deficiencies Identified
   a. Pertussis Assay Validation
   b. Diphtheria and Tetanus Assay Validation
   c. Performance Qualification for equipment and utilities
   d. Stability on polysaccharides
   e. Detailed SOPs for all the analytical methods involved in the preparation, characterization and quality control of the in-process intermediates,

The drug substance and drug product SOPs are not necessary, they can be removed from the major deficiencies letter.

   f. Deviations and corrective actions, container closure data, cleaning sterilization, depyrogenation and filling process validation data

This should be combined with "c"
There will be stats comments forthcoming. There is concern over many protocol

deviations for P13 involving two sites specifically, #44 and #50. BIMO has picked 4 sites, and #44 is amongst them.

4. Upcoming events (before calendar year end)
    a. no VRBPAC,
    b. Proprietary name review completed, - *there will be another review 90 days before the action due date.*
    c. PeRC/PREA – set date- *there were some questions on the timing of this. It seems that this is too early.*
    d. lot release testing plan,
    e. BIMO scheduled, - *The sites have been picked and a draft plan is in the works.*

There is quite a bit of concern over the timing of the final review due date. The two inspections (BIMO and Compliance) will be performed in the Jan- Feb time frame. If there are issues (i.e.483s), there is no time for the companies to respond (they have a 60 day response time) and to finalize the reviews with this due date of March 26, 2009. Similar issues were raised for BIMO inspection.

5. Documents – Reviews, memos, telecons, emails, meetings summaries, etc.
    a. All deadlines include uploading **signed, 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)
6. Communication with sponsor - *If anyone has any request for information, Cara can facilitate. Please contact her.*
7. 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
Meysick, Karen- Assay Validation
Miller, Catherine- APLB
Pratt, Doug- Clin Chief (cc)
Richman, Paul- Branch Chief (cc)
Roecklein, Tina- Product Coord
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

8. 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. If needed	27Oct08
Filing Action	>28Oct08
Deficiencies identified	>11Nov08
Draft Reviews Due/Mid Cycle review	**25Jan09**
VRBPAC planning meeting	26Nov08
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)	Every Month
IOD Monthly Update (WV/CF)	Every Month

9. November Meeting – November 19th (Wednesday) 3-4 pm – appt to be sent out
10. December Meeting – December 17th (Wednesday) 3-4 pm tentative.
11. Questions/Comments/Concerns?