Summary of November Monthly Meeting - Menveo

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BLA 125300_0
Novartis ACYW-135 Mening Vaccine
W. Vann, Chair
C. Fiore, E. Valenti, reg coordinators

1. Introductions – *Betsy Valenti will be our back up coordinator.*

The following people attended either by phone or in person:
Al-Humadi, Nabil
Bash, Margaret
Blake, Milan
Burns, Drusilla
Campbell, Karen
deVore, Nikki
Fiore, Cara
George, Joe
Lee, Martha
Lee, Robert
Meysick, Karen
Miller, Catherine
Sun, Wellington
Roecklein, Tina
Valenti, Elizabeth
Vann, Willie

2. DI letter has been sent
3. Review Team Reports

a.

a.

a. **Clinical** – *a PREA date has been requested.*
b. **Statistical** – *no update*.
c. **BIMO** – *The following 4 CI inspection assignments were issued Nov 6, 2008:*

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- *Stan Block, Site 53, 347 subjects, Kentucky*
- *Henry Bernstein, Site 44, 227 subjects, New Hampshire*
- *Keith Reisinger, 16 sites, 774 subjects, Pennsylvania*
- *Roger Baxter, 6 sites, 630 subjects, California*

d. **DPQ** - *DPQ reviewers have been assigned to review analytical methods and validation data. They want to be involved in creating a lot release protocol; providing testing and support; and putting together a testing plan for bulk and final container methods. There are some in-process*

unvalidated method issues that are being reviewed.. Jan 15th is date for the internal review to be drafted.

e. **DMPQ** *–coordinating when then pre-licensing inspection may occur; mid Feb. probably. The --b(4)----site will be waived for inspection. This is where the fill finish takes place.*

f. **Product** *– methods are abbreviated, there is lack of description of methodology. ----b(4)---------- ---------- ---------- There are details that need to be addressed such as -b(4)- used for the -b(4)- assay, but no major issues. There are several typos that need clarifying as well.*

g. **Labeling** *– this will not be addressed until later in the review. There should be consistency with other package inserts.*

h. ***T*oxicology** *– no update*

i. **Reproductive Toxicology** *– not too much, except data WRT to pup mortality during early postpartum period but that occurred across study groups and may be within historical control. However, Novartis has proposed language in section 8.1 of the draft product labeling (pregnancy section) that follows the format of the proposed rule entitled "Content and Format of Labeling for Human Prescription Drug and Biological products; Requirements for pregnancy and lactation labeling" (May 29, 2008). Since the proposed rule is not finalized, the pregnancy labeling section 8.1 must include a pregnancy category and language as prescribed in current 21 CFR 201.57(9)(i)(A).*

j. **Assay Validation (concomitant and hSBA)**

i.

i.

i.

i. OBE stat assay – *will meet with the product assay reviewers*

ii. hSBA assay – *this assay is the same as in the IND. No major problems. But there is no formula for interpretation of data. Values for Mening A seem low, both across studies and across products.*

iii. Concomitant vaccines – *When should they expect responses to the DI letter for the assay validation? Novartis should submit something this week.*

k. **OBE/PMS** *– no update.*

4. Upcoming events (before calendar year end)
   a. PeRC/PREA – set date,
   b. Lot release testing plan,
   c. Pre-Licensure Inspection – set date,
   d. BIMO plan forwarded.
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 - *all emails, telecons, etc., must be captured in the EDR.*
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
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
Schwab, David- Elect. Integ
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

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

Milestones	**Date**
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. December Meeting – December 17th (Wednesday) 3-4 pm tentative.
   OVRR action update Dec 17th. May have to reschedule. Stay tuned.
10. Questions/Comments/Concerns?
    Ongoing concern about tight review deadlines