# Monthly Meeting, December 17, 2008 - Menveo

- BLA 125300_0
  Novartis ACYW-135 Mening Vaccine

**December Monthly Meeting**

| Date | Time | Location | US Call in | Password | International Call in - Toll |
|---|---|---|---|---|---|
| Wednesday Dec 17, 2008 | 2:00 – 3:00 EST PM | ROOM **400 North** WOC- 1 Building | ---b(4)---------- --- | Participant Passcode -b(4)------ Leader pass code --b(4)--- | ----b(4)---------- ---- |

1. Introductions – please sign in
   a. Willie Vann, Chair
   b. Cara Fiore, Elizabeth Valenti – Reg Coordinators
   c.

*The following people attended either by phone or in person:*
*Bash, Margaret*
*Blake, Milan*
*Burns, Drusilla*
*Campbell, Karen*
*Fiore, Cara*
*George, Joe*
*Gruber, Marion*
*Gupta, Rajesh*
*Krasnicka, Barbara*
*Lee, Martha*
*Lee, Robert*
*Meysick, Karen*
*Miller, Catherine*
*Trudell, Nicole*
*Sun, Wellington*
*Roecklein, Tina*
*Valenti, Elizabeth*
*Vann, Willie*
*White, Janet*

2. Recent amendments (0.1, 0.2)
3.
   3. CMC 0.1 Nov 21, 2008
      i. optimizing CRM 197 innocula
      ii. Extractables and Leachables
   c. Clinical 0.2 Dec 5, 2008: SAE reports (11)

3. DI response deadlines?
    a. Concomitant assay validation (TDaP) –
        i. *Pertussis –*
            1. *There are two studies, P18 and P11 for concomitant use. The P11 study is the pivotal supportive study that uses the --b(4)---------- for the concomitant use. Novartis has submitted some data to the IND (not BLA) that addresses some BLA questions for the -b(4)- labs (to support the P18 study), but nothing has been submitted for --b(4)---------- assay validation. Additionally, Novartis must submit this to the BLA to be considered.*
            2. *Novartis has been told that they have to submit the information for review to the BLA.*
            3. *There was a vaccine failure (reduced protection) for pertussis with Menactra, so this should be stated in the label. We may get questions regarding adolescent immunization and concomitant use.*
        ii. *TD – The information is now included in the IND, but Novartis needs to submit this to the BLA.*
    b. Manufacturing (PQ, stability) – *Since the pre-Approval Inspection is scheduled for Feb 16-28th, we would like to get the requested DI information in by Jan. 5th.*
    c. Statistical – *The reviewer would like to see this information come in before December 25th.*
4. Review Team Reports - Please bring to the attention any concerns or questions you have on your sections.
    a. Clinical – *there were unblinding issues at two of the largest sites. It was considered a minor deviation. If it were a major deviation, Novartis would not be able to use the information from this site. At the Dartmouth site, the list of what the subjects received was found in the folder of the study investigator. They are performing additional analysis to insure this did not impact the study. PERC is April 22, 2009.*
    b. Statistical – *updated above.*
    c. BIMO- *no update.*
    d. DPQ – *the Product reviewers will meet with DPQ, during the first week in January, to determine what should be tested. Novartis should submit a template of the lot release protocol. DPQ is aiming to have a final draft of their review by mid February.*
    e. DMPQ – *updated above.*
    f. Product – hSBA assay – *there are a couple outstanding linearity questions that should be conveyed to the sponsor.*
    g. Labeling – *Regarding the reproductive toxicology (pregnancy) section – There is a new proposed format that is not yet finalized. The proposed label submitted by is in the new format, however because this new format is not approved it cannot be used.. In CDER, they are using a hybrid format, both old and new, for their label. We can do that too, but it will take some re-wording and concurrence with the sponsor. The developmental toxicology data is fine.*
    h. Toxicology – no update.

i. Reproductive Toxicology – *They use rabbits in their pivitol study and they have a dose ranging study. The historical controls are fine and so far there are no concerns with the data.*
j. Assay Validation (concomitant and hSBA) – There are questions of interpretation and a need for explanation of some information submitted to the BLA. This will be sent to Novartis as an IR request.
k. OBE/PMC –Postmarketing studies were proposed by Novartis, however once all of the data is reviewed we will probably need to ask for additional studies to be performed.

5. Upcoming events
   a. Action package officer/employee list - *You will receive an email to vote whether you would like you name on the employee list included in the action package.*
   b. Reviews due and posted in the event of a CR – *this is a case by case basis, but OCC has interpreted the new FDAAA regulations to say that the information may be posted in the event of a CR.*
   c. PeRC/PREA – *April 22, 2009*
   d. VRBPAC – need justification for not going. *There is template language for this that the Chair can use to justify the review teams decision.*
   e. Lot release testing plan – The team *will meet during the first week of January, 2009.*
   f. BIMO inspection - *on assignment*
   g. Pre-Licensure Inspection - February *16 – 28, 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 sponsor and email them to regulatory coordinators and Chair. They will have to be listed on the documentation review spread sheet for the Division Director.

*Betsy Valenti presented a table that lists what will be all communications and the result of the communications with the sponsor that OVRR management is requiring to be a part of the Action Package. It must be kept up to date, so please email her any communication and the outcome of the communication in a timely manner.*

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
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

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. | 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 |

9. Next Meetings –

a. Jan 14, 2009 (Wednesday) 3-4:30 pm MID CYCLE REVIEW. This will be a longer meeting. Please plan on providing to the team where you are in your review. (This meeting is considered a milestone).
b. Feb 11, 2009 (Wednesday) 3:00 -4:00

10. Questions/Comments/Concerns? – No additional concerns.