Review Committee Meeting Summary, November 12, 2009 - Menveo

BLA 125300_0
Novartis ACYW-135 Mening Vaccine

November Review Committee Meeting Agenda

Date	Time	Location	US Call in	Password	International Call in - Toll
Thursday November 12, 2009	3:00 – 4:00 EST PM	Room 300 N, in Building WOC 1	---b(4)---------- --	Participant Passcode --b(4)---- Leader pass code --b(4)---	---b(4)----------

1. Attendees
   Al-Humadi, Nabil
   Bash, Margaret
   Campbell, Karen
   Fiore, Cara
   Freedberg, Daron
   Gupta, Rajesh
   Krasnicka, Barbara
   Lee, Martha
   Stewart-Bennett, Daphne
   Sutkowski, Elizabeth
   Vann, Willie
   Valenti, Elizabeth
2. Recent Amendments
   a. Running list
      i. optimizing CRM 197 innocula (0.1)
      ii. Extractables and Leachables (0.2)
      iii. Partial DI response (0.3)
      iv. Partial DI response and additional info (0.4)
      v. Response to IRs. (0.5)
      vi. HPV V59P18 (0.6)
      vii. Pharmacovigilance Response (0.7)
      viii. Correction to LIMS and updated product list (0.8)
      ix. PerC Deferral Information (0.9)
      x. 483 response (.10)
      xi. Batch records and product samples (.11)
      xii. Stability Data for 24 months and packaging mock ups
      xiii. Specifications and validation of specs, manufacturing data
      xiv. Pharmacovigilance plan, ---b(4)----------, updated 483 responses, Comparability Protocol
      xv. Complete Response (Aug 21, 2009)

xvi. Pre-licensure testing – selection of batches (Oct 8, 2009)
xvii. Stability data to 36 months, batch data for pre-licensure testing, PVP

3. Team Reports
   a. Clinical – *the IND continues to dominate the majority of the review time. Last week the sponsor was told that focus needed to be put on the BLA, not the IND; however, they then submitted more amendments to the IND. The sponsor wants answers on retesting in the infant P14 study and toddler P21 study . Dr. Bash agreed to draft language, for review by OVRR management, to gain support for only reviewing the BLA at this time.*
   b. Statistical – *the P14 submission for the IND was also reviewed and a new analysis plan was (for an assessment of agreement of the original test and re-test procedures) proposed. Review of the BLA will continue next week.*
   c. CMC – Daron Freedberg – *the sponsor wanted --b(4)---------- however, rational for ---b(4)---------- was not satisfactory. The review is in draft form and the ----b(4)----------. An IR will be sent to the sponsor asking -----b(4)----------*
   d. Lot Release – *Problems should be identified and comments should be sent to the sponsor by mid-December. The final review memo should be completed by January 15, 2010.*
   e. Labeling – *APLB review finished. The first labeling meeting is November 17, 2009. OBE, APLB, DE, and Repro Tox have sent comments. Dr. Vann will review the drug description prior to the labeling meeting.*
4. Major Due Dates are on Table below

Milestones	**Date**
Lot release protocol	asap
Lot release testing (consist and launch)	10/20/09
Labeling - start	**Oct/Nov**
Further BIMO/CMC inspection?	
Another facility inspection?	
Deficiencies Identified	11/03/09

Milestones	Date
Midcycle Review	11/04/09
Prep of product testing plan	11/04/09
Final Prop name review	11/19/09
Final Reviews Due	**12/19/09**
PMC to FDAAA Safety WG	
Action Package routing	1/13/09
Lot release clearance	01/18/10
Approval letter draft	1/19/09
Action Package to Branch Chiefs	1/20/10
Final Action Due Date	**2/20/10**
Action Package Posting	**2/20/09**
Monthly Meetings (Team report)	monthly
IOD Monthly Update	monthly

5. Next Meeting –
   a. December 9, 2009
6. Questions/Comments/Concerns?
   a. Please continue to include Cara and Betsy on emails.

7. Action Items
   a. *Dr. Bash to draft language, for review by OVRR management, to gain support for only reviewing the BLA at this time.*
   b. *Dr. Freedburg to draft an IR asking that the tests be added back to the plan.*