Novartis (Agrippal) STN 125297
Committee Meeting Minutes 7/28/08

Agenda:

1. Review milestones
2. Discuss review assignments
3. Discuss review strategies
4. Discuss inspection

Milestones:

Application Received:	July 11, 2008
Committee Assignment	July 21, 2008
1st Committee Meeting	July 28, 2008
Filing Meeting	August 22, 2008
Filing Action	**September 9, 2008**

SOPP can be viewed at <http://www.fda.gov/cber/regsopp/8404.htm>.

Deficiencies Identified **September 23, 2008**

SOPP can be viewed at http://www.fda.gov/cber/regsopp/84013.htm. Letter template can be viewed at[----------high b(2)----------]

First Action Due **May 11, 2009**

Committee Assigned, areas of expertise:

Anissa Cheung (RP), Chairperson, Regulatory
Vada Perkins (VP), Regulatory Coordinator/EI Review
JP McWatters (JP), Regulatory Coordinator/EI Review
Melisse Baylor (MB), Clinical
Tsai-Lien Lin (TL), Biostatistics
Patricia Rohan (PR), Epidemiology
Joseph Manik (JW), BiMo Monitoring
Ira Berkower (IB), Product
Rajesh Gupta (RG), Product support
Lisa Stockbridge (LB), APLB
Pete Amin (PA), Facilities
Dave Green (DG), Toxicology
Marion Gruber (MG), Repro. Tox

EDR Contacts:
Yudha Rustaman 301-827-1381

Tentative Review Assignments

1. Labeling:
   a. Package Insert: LS (all) MB (all), AC (all), VP (all), JP (all), IB (all)
   b. Containers and Packaging: AC, JP, VP

2. Summary: Everyone

3. CMC section: IB, PA, RG
   Environmental Assessment/Categorical Exclusion-PA

4. Nonclinical: DG, MG

5. Clinical:
   Pivotal, non-pivotal and supporting clinical studies, Pharmacovigilance plan – MB, PR, TL

6. Statistical – TL, PR, MB

7. Case Report Tabulation – TL, JM, MB

8. Case Report Forms- MB, JM

9. Debarment Certification – JP, VP

10. User Fee Cover Sheet – David Dickerson (DVRPA), RIMS, JP, VP

11. Financial Disclosure – JP, VP, AC

12. Electronic Integrity-VP, JP

Discussion Items:

A. Point of Contact between Nova and CBER: JP

B. Communication Documentation:
   1. All communications with Nova should be coordinated through JP. JP/VP are responsible for documenting calls from Nova.
   2. In the event there is a reviewer initiated communication, reviewer will be responsible for writing up telecons with Nova.
   3. All internal documents are electronic, JP/VP need all documents, e.g., reviews, telecons, etc. electronically. JP/VP responsible for entering communications into RMS-BLA.
   4. Preference for at least 2 CBER personnel on all major telecons.
   5. Review memos are to state what was reviewed with reference to the associated amendment. Comment references should be linked to the CTD file and include the page number within that specific CTD file.
      -Supports Chair Memo, Documentation Review Memo, and Leadership Sign-Off.

C. Inspections:
1. Bioresearch Monitoring: Joe Manik
2. Facilities: Pete Amin

D. CMC:

E. Nonclinical: Requested that Joe Sun review the file to confirm that there were no RTF issues because Dave Green would not be available until 8/11/08. Dave actually returned on 8/4/08 and agreed to review the file for deficiencies.

F. Clinical:

G. Labeling (PLR):

H. PREA: PERC, Melisse Baylor

I. VRBPAC-N/A – as of yet there is no reason to have a VRBPAC

J. PMC/PMR: Trish Rohan, Melisse Baylor

K. **Next Step:**
Determine acceptability for filing and identify any review issues. Filing meeting is scheduled for **August 22, 2008**.

L. Goals:

1. Draft reviews completed by mid-cycle – **December 11, 2008**. Completed and signed off reviews due by **March 31, 2009.**
2. (**AD: May 11, 2009**)-Approval package to leadership by **April 11, 2009**.