

# Committee Filing Meeting - April 6, 2009

## STN 125347 Committee Filing Meeting

**Date:** April 6, 2009

### Summary:

Filing meeting conducted via e-mail. The initial e-mail was sent April 2, 2009 and all available committee members responded by April 6, 2009. The unanimous decision was that the BLA may be filed.

APLB has reviewed the Proprietary Name Submission and determined that it is complete. The 90 day milestone (June 29, 2009) has been added to RMS-BLA.

DMPQ reviewers have presented a deficiency to the committee to be included in the Deficiencies Identified Letter:

Please provide container closure integrity PQ/validation data for the Container Closure System. This data was not included in section 3.2.P.7 of your BLA submission. Also, please include summary data of any extractables/leachables studies.

No other issues were discussed.

### Milestones:

<b>Application Received:</b>	March 17, 2009
<b>Committee Assignment</b>	March 24, 2009
<b>1<sup>st</sup> Committee Meeting</b>	March 31, 2009
<b>Filing Meeting</b>	April 2, 2009 (via e-mail)
<b>Filing Action/Deficiencies Identified</b>	April 16, 2009
<b>Target Action Due Date:</b>	July 31, 2009

**Committee Chair:** Jay Slater, M.D.

### Committee Members

<b>Clinical Reviewer/Labeling</b>	Karen Farizo, M.D.
<b>Product CMC/Serology</b>	Mustafa Akkoyunlu, M.D. Ph.D,
<b>Product CMC</b>	Scott Norris
<b>Product CMC</b>	Tina Roecklein
<b>Facilities/DMPQ</b>	Joseph George
<b>Advertising/ Promotional Labeling</b>	Maryann Gallagher
<b>Clinical Statistical Reviewer</b>	Ghideon Ghebregiorgis, Ph.D.
<b>Epidemiology</b>	David Menschik, M.D., MPH
<b>DPQ/Lot Testing Plan</b>	Rajesh Gupta, Ph.D.
<b>Lot Release</b>	Joe Quander III
<b>BiMo</b>	Christine Drabick, MS
<b>DVRPA Reviewer</b>	Joe Temenak, Ph.D.

### RPMs/RC

<b>DVRPA Regulatory Project Mgr.</b>	Jason Humbert
<b>DBPAP Regulatory Coordinator</b>	Jennifer Bridgewater, MPH

