Agenda for discussion on sterility assay and respective method validation (Date 07.22.2011; 1:30 PM)

Documents to be discussed:

1. response-fda-questions-06-15-17-2011.pdf (from BLA submission 125397.007)
2. sop-cb40-0006-3.pdf (from BLA submission 125397.007)
3. sterility-assay-validation-summ.pdf (from BLA Original Application)

Topics of discussion (reference: response-fda-questions-06-15-17-2011.pdf):

1. Response to FDA question 27 (v):
   i. Please update the Table 1 by using all the six release criteria described under the submitted sop-cb40-0006-3.pdf (page 26).
   ii. Please indicate where "+" and "++" should go in Table 1.

Sponsor response: The sponsor will submit an updated table before Aug 15th, 2011

2. Response to FDA question 31 (i):

   Please submit the requested information by August 15th, 2011.

Sponsor response: The sponsor will submit the requested information before August 15th, 2011.

3. Response to FDA question 32:

   Please submit the requested information by August 15th, 2011.

Sponsor response: The sponsor will submit the requested information before August 15th, 2011.

4. Response to FDA question 34 (i):

   During our previous telephone conversation on June 28th, 2011 you told us that for the Phase II of your validation studies you have used ----------(b)(4)----------as submitted in the documents response-fda-questions-06-15-17-2011.pdf and sterility-assay-validation-summ.pdf).

   Please revise the following as necessary in the document sterility-assay-validation-summ.pdf and submit it for our review by August 15th, 2011

   i. ----------(b)(4)----------
   ii. -----(b)(4)-----
   iii. ----------(b)(4)----------.

Sponsor response: The sponsor will rewrite the respective section of the validation study as requested above and submit it for our review before August 15th, 2011.

5. Response to FDA question 35:

    Please submit the requested information by August 15th, 2011.

Sponsor response: The sponsor will submit the respective experimental protocol for our review before August 15th, 2011. The actual data for --(b)(4)-- will be available by the end of August and for -----(b)(4)------- by the end of September.

6. Response to FDA question 38:

    Please submit the requested information by August 15th, 2011.

Sponsor response: The sponsor will submit the requested information before August 15th, 2011.