

Discussion Points Email, February 09, 2012

- Ducord

From: Gavin, Denise K
To: Gavin, Denise K; "[Amanda Parrish, Ph.D.](#)"; "[Bruce Burnett, Ph.D.](#)";
cc: Davidson, Mark;
Subject: RE: Discussion points
Date: Thursday, February 09, 2012 4:58:59 PM
Attachments: (b)(4)review items BLA 125407 2-9-12.doc

Amanda

Please see the attached information request for the -----(b)(4)----- methods and validation (these items were also discussed during 1-6-12 teleconference).

Unless there are questions with the request we would like to wait until 2-22-12 to further discuss these items.

Thank you, Denise

From: Gavin, Denise K

Sent: Thursday, February 09, 2012 4:29 PM

To: 'Amanda Parrish, Ph.D.'; Bruce Burnett, Ph.D.

Cc: Davidson, Mark

Subject: Discussion points

Amanda and Bruce,

In order to expedite the review process, we would like to set up two teleconferences to discuss outstanding CMC issues.

Please have relevant quality control folks present if possible to make these discussions more efficient.

1) Review of the CD34 -----(b)(4)----- methods and validations is not possible without additional information.

We would like to set up a meeting on Monday 2-13-12 at 2 pm to give you a list of items we need to work on this review.

2) We would also like to set up a teleconference to discuss the status of all outstanding issues following the midcycle date (2-16-12).

Wed 2-22-12 from 11:30-12:30 works for everyone on our end.

Please let me know if we can schedule discussions on these dates.

Thank you,

Denise

Denise K. Gavin, Ph.D. Expert Biologist

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