

Assay Procedures Email, February 13, 2012

- Ducord

From: Gavin, Denise K
Sent: Monday, February 13, 2012 4:42 PM
To: 'Amanda Parrish, Ph.D.'; Davidson, Mark
Subject: RE: BLA 125407- ----(b)(4)---- Assay Procedures

Amanda-

Thank you, and please submit to file as this SOP/information is relevant, since the (b)(4) assay is part of potency testing and we asked for validation and comparability data for (b)(4) assays performed at Duke Stem Cell Lab (fresh) vs Robertson Clinical Translation Lab (post-thaw potency). Hopefully this additional information will be available soon.

As a heads up to additional information we will be requesting, the description and SOP for TNCC, ---(b)(4)--- and (b)(4) counts by (b)(4) states that when values are "voted out" these values will be determined -----(b)(4)----- . I have not seen this assay described nor did I find the SOP in the original submission, was it included? If so, could you please indicate where it can be found? SOP number? or submit it please. Please note that since TNCC and (b)(4) are vital to product quality assessments, the - (b)(4)- assay will need to be validated.

You have submitted a number of files as emails which at this point are still considered informal submissions, any idea when these will be added to the file?

Thank you, denise

From: Amanda Parrish, Ph.D. [mailto:amanda.b.parrish@duke.edu]
Sent: Monday, February 13, 2012 3:52 PM
To: Gavin, Denise K; Davidson, Mark
Subject: BLA 125407- -----(b)(4)----- Assay Procedures

Denise and Mark,

Since your team requested the viable CD34+ procedure from the Duke Stem Cell Lab earlier this month, we thought that you might also want to have the relevant SOPs for the -----(b)(4)----- assay (b)(4) performed in that lab. These procedures were not included in our original submission.

We will note that this procedure has been recently revised, and there may be a few discrepancies with the (b)(4) narrative in the original BLA. We commit to updating this section of the BLA but thought that these SOPs might be beneficial for your review. If you agree that these are needed, we will also send these formally to the SOP section of our application.

Thanks-

Amanda

Amanda B. Parrish, PhD, RAC
Regulatory Affairs Scientist
Duke Translational Medicine Institute
phone: 919.668.8772
fax: 919.668.7868
email: amanda.b.parrish@duke.edu

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