

Teleconference - BLA update discussion, May 2, 2012 - Ducord

125407/0 5-2-2012 teleconference minutes

Duke: Amanda Parrish, Ph.D.

FDA: Mark Davidson, Denise Gavin

Re: BLA update discussion

Dr. Parrish requested a brief t-con to discuss how to submit the remaining information to the Duke BLA (#125407). Duke plans to submit process and method validation study reports and supporting SOP, stability data and protocol, and donor eligibility information in the next month or so (see AP email below).

We informed Dr. Parrish that Duke could submit one copy of the BLA amendment and include a CD with tracked changes to the particular BLA sessions, as well as a clean version.

We also discussed the possibility that at this late stage of the review process (<90 days until the July 9, 2012 action date), that the amendment will likely be considered a major amendment which would extend the BLA review clock by 90 days.

We explained the process of major amendment review and a copy of the SOPP 8402: Designation of License Application Amendments as Major was sent in a subsequent email (see DG email below).

Dr. Parrish understood this process and the possibility of a delayed action on the BLA decision. AP stated that Dr. Burnett may have additional questions, and they may want another t-con.

She stated that Duke will submit the amendment by the end of May and will also provide pdf files for the review team. She also stated that they will be submitting a separate amendment containing the information requested by Dr. Karandish (i.e., donor eligibility and tracking information).

Call ended.

From: Amanda Parrish, Ph.D. [mailto:amanda.b.parrish@duke.edu]

Sent: Tuesday, May 01, 2012 12:24 PM

To: Gavin, Denise K

Subject: RE: quick 5 minutes to discuss BLA updates

Denise,

I was more hoping to run by you our plan for getting the Agency the needed revisions to the BLA documents themselves. I realize that we are currently right around 60 days until our action date, and we are working really hard to get everything done/submitted as quickly as possible. I think we've tracked what needs to be addressed, and we plan to update each section of the BLA as applicable in addition to submitting revised SOPs/validation reports as appropriate.

We hope to have all of this done by the end of the month if not earlier. We have been assuming that your team would need to review these changes prior to licensure, and we were just trying to brainstorm to see if there was a more efficient way to highlight these changes for the reviewers. Perhaps just sending in new paper copies would be sufficient.

Amanda

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From: Gavin, Denise K [mailto:Denise.Gavin@fda.hhs.gov]

Sent: Wednesday, May 02, 2012 1:25 PM

To: Amanda Parrish, Ph.D.

Subject: RE: quick 5 minutes to discuss BLA updates

Amanda

Here is the SOP related to major amendments to a BLA. Thank you for clarifying your plans.

Denise

<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ProceduresSOPPs/ucm073461.htm>

Thanks

Page Last Updated: 11/02/2012

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