Amendment 018 Email, September 21, 2012 - Ducord

From: Gavin, Denise K
Sent: Friday, September 21, 2012 2:25 PM
To: Davidson, Mark
Subject: FW: Amendment 018
Mark please add this to EDR. thank you. d

From: Gavin, Denise K
Sent: Friday, September 21, 2012 2:24 PM
To: 'Bruce Burnett, Ph.D.'; Amanda Parrish, Ph.D.
Cc: Davidson, Mark; Wonnacott, Keith
Subject: RE: Amendment 018
Bruce
In addition to the validation and comparability report of the ---(b)(4)--- thawing procedure, please include also submit the following outstanding items:
1) the revised stability protocol (not data) with revised acceptance criteria (i.e. (b)(4) units must past sterility) and additional information regarding the use of ------(b)(4)------- thawing processes and how that will or will not affect % recoveries.
2) the revised Process Validation protocol which accurately reflects the method used to thaw units.
"And as mentioned above, STCL-PROC-034 was listed in the process validation report submitted in Amendment 14 on August 15, 2012. This was incorrect and STCL-SOP-028 and STCL-PROC-036 should have been listed. This error will be corrected and the amended validation report submitted to the BLA."
3) Please comment as to whether you still intend to include documents with Ducord, that are not FDA approved (i.e. AABB COI).
You previously stated that "Communication with FACT suggests that while the COI is currently required, revised standards are being circulated for review in September 2012 with the following change:
E4.5 A circular of information or package insert and instructions for handling, thawing, and using the CB unit, including short-term storage and preparation for administration, shall accompany the CB unit. (Bolding and italics added for emphasis).
Thank you,
Denise
Denise K. Gavin, Ph.D.
Expert Biologist
Gene Therapy Branch
FDA/CBER/OCTGT/DCGT

Rockville, MD 20852
301-827-5102

From: Bruce Burnett, Ph.D. [mailto:bruce.burnett@duke.edu]
Sent: Friday, September 21, 2012 12:11 PM
To: Gavin, Denise K; Amanda Parrish, Ph.D.
Cc: Davidson, Mark; Wonnacott, Keith
Subject: RE: Amendment 018
Denise,

Yes, we do have a report, which I have attached and will submit formally to the BLA today.

Bruce

Bruce K. Burnett, PhD, RAC
Director of Regulatory Affairs
Duke Translational Medicine Institute
Duke University School of Medicine
Phone: 919 668-7178

From: Gavin, Denise K [mailto:Denise.Gavin@fda.hhs.gov]
Sent: Friday, September 21, 2012 12:07 PM
To: Bruce Burnett, Ph.D.; Amanda Parrish, Ph.D.
Cc: Davidson, Mark; Wonnacott, Keith
Subject: Amendment 018

Hi Bruce

When do you plan to submit the information related to STCL-SOP-036 validation and comparability between -----(b)(4)------ Thaw/wash procedures used for stability protocol?

This information is necessary since STCL-SOP-036 is part of the stability protocol to extend the expiration date on a yearly basis. I do not have data to support control of that procedure for establishing stability going forward.
Based on an email from JK on 9-17-12, I expected this information on 18SEPT2012 or at least in the amendment submitted today, but I did not see it there. The stability protocol needs to be finalized today or a revision submitted as a supplement. I need this information by 1 pm today to complete our review.
This information can also be submitted as a supplement to the BLA if you are not ready to submit today. We will simply change our memo to state that the stability protocol is not yet acceptable and will be revised as a supplement to include the above requested information. This may also be the case it upon reviewing the data I have additional questions.
I am hoping this submission was just lost in the rush to get the thaw wash instructions revised.
Please advise as to your plans.
There are other minor issues that need to be addressed and I will send another email later with that information.
Thank you,

Denise

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https://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ApprovedProducts/default.htm