Response to Review Issues, December 2, 2011 - Ducord

From: Gavin, Denise K
Sent: Friday, December 02, 2011 9:50 AM
To: 'Amanda Parrish, Ph.D.'
Cc: Davidson, Mark; Karandish, Safa; Bruce Burnett, Ph.D.; Wonnacott, Keith; Takefman, Daniel
Subject: RE: Response to Review Issues for BLA 125407

Dear Amanda

A formal response to the Nov 7th letter by Mid December is fine. I remind you that the more thorough the information the more efficient our review will be.

Regarding the SOP for emergency product recovery plan, I will attempt to clarify: in the submission it appeared as though there was no plan in place, which is not acceptable. Please provide an SOP/plan for review.

The CBU should be accompanied by instructions for limiting CBU/product damage during handling/thawing and an SOP for product salvage should unanticipated problems arise. The SOP should include instructions to the transplant center as to what to do in case of product damage, (such as steps to reduce possible contamination, plans to ensure sterility, instructions for recovery of the product, and instructions for contacting CCBB, transplant physician(s) and other relevant personnel in a timely manner in the event of damage). The SOP could also include instructions for investigation of product damage, if warranted. The transplant center will likely make the decision to use the product or not based on individual circumstances.

I hope this is helpful.

Thank you,

Denise
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therefore not legally binding.

From: Amanda Parrish, Ph.D. [mailto:amanda.b.parrish@duke.edu]
Sent: Wednesday, November 30, 2011 4:17 PM
To: Gavin, Denise K
Cc: Davidson, Mark; Karandish, Safa; Bruce Burnett, Ph.D.
Subject: Response to Review Issues for BLA 125407

Dr. Gavin,

I spoke with Mark Davidson on the phone today regarding the review issues that were raised in the Nov. 7th filing letter for BLA 125407. He requested that I follow-up with an email to ensure that our plan for responding to these issues is acceptable.

Our current plan is to provide a formal response to each of these issues in mid-December. In some cases, this may be our complete response to resolve your concern (for requested SOPs) or it may be a more detailed timeline of how we plan to address the concern (for the validation/comparability studies requested). For the validation studies requested, our goal is to submit with this initial response a validation protocol for which the Agency could potentially provide comments as appropriate. We expect that some of the final validation reports may not be available until early 2012.

Can you please advise on if you find this approach acceptable? We are working as hard as we can to ensure that the FDA receives the requested information as quickly as possible.

Furthermore, our team wanted to request clarification on the request for an SOP on the emergency product recovery plan. Specifically, there is some internal confusion about exactly what this plan should encompass. From reading the HPC-C guidance, it seems that the FDA wants a plan/SOP for cases where the HPC-C product bag may break in transit to the transplant center (or, during the transplant center's thawing process). Should this include decisions about what happens to the product itself (i.e. Is it infused?) or just how we would investigate this issue internally? Can you provide some clarity here? I would be happy to correspond with you regarding this issue in a separate email or via phone as needed.

Thanks-

Amanda
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