From:	Janice Castillo
To:	Gildner, Jean
Subject:	Re: BLA 125586 Clarification on Information Requests
Date:	Thursday, February 01, 2018 4:06:55 PM
Attachments:	image001.png

Jean,
Receipt acknowledged.
Also, please extend our thanks to the review team for the rapid turnaround. Having the information helps us to complete these specific responses more expeditiously.
Janice

Sent from my iPhone

On Feb 1, 2018, at 12:15 PM, Gildner, Jean <Jean.Gildner@fda.hhs.gov> wrote:

> Dear Janice,
>
> We appreciate your request to clarify our information request. Please see our response below. Please acknowledge receipt of this email.
>
> <!--[if !supportLists]-->*1)* <!--[endif]-->***Subject*** (b) (6) ***experienced chest pain lasting 1 day and occurring 21 days post andexanet infusion, please provide a narrative that includes work up to exclude cardiac or pulmonary (embolic) causes.***
>
> The documentation for subject (b) (6) does not show that the subject experienced chest pain. However, subject (b) (6) did. Was this just a transposition error and should we be looking at subject (b) (6) ?
>
> **FDA:** Yes, we apologize for the error, the subject in question is (b) (6) .
>
> <!--[if !supportLists]-->**2)** <!--[endif]-->***Subject*** (b) (6) ***appears to have numerous AEs that are unlisted in the ADAE dataset with AE start and end dates provided. Please update the ADAE data table. Please also provide the CT reports from 04/06/17 and 03/08/17*** ***Please confirm if FDA is asking for coding on the uncoded AEs.***
>
> **FDA:** Yes, please include the dictionary derived terms.
>
> <!--[if !supportLists]-->**3)** <!--[endif]-->***The following subject deaths have not been listed in Table 16 of the addendum to the CSR:*** (b) (6) ***. Please confirm that these subject deaths occurred.*** ***Please confirm the accuracy of patient number*** (b) (6) ***. Portola does not have a record for a patient*** (b) (6) ***or a site number 15***
>
> **FDA:** We apologize for the error, the subject ID in question, (b) (6) is incorrect. The correct subject ID is (b) (6)

<!--[if !supportLists]-->4) <!--[endif]-->In FDA's assessment of Adverse of Special Interest, we are including the following events as a) ischemic causes cannot be ruled out as contributory to the cardiogenic shock, CHF or acute respiratory failure or b) were related to thrombotic events were :

1) Cardiogenic shock and Congestive heart failure

2) Acute respiratory failure (unexplained by pneumonia or other non-ischemic causes)

3) Cardiac thrombus (classified as thrombotic event)

4) Iliac artery occlusion (classified as thrombotic event)

We are unclear as to the information or action the FDA is requesting, and respectfully ask for clarification.

FDA: We are not requesting a specific response at this time, but the advice is intended as an interactive process to assist you with understanding the basis for the FDA's safety analysis. You may wish to consider conducting an analysis of the AESI using the protocol specified AESI together with the criteria mentioned above.

Sincerely, Jean

Jean F. Gildner MSHS, MT (ASCP)
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<image001.png>

<image002.jpg> <image003.jpg> <image004.jpg> <image005.jpg> <image006.jpg>