

From: [Janice Castillo](#)
To: [Gildner, Jean](#)
Subject: Re: BLA 125586 Information Request
Date: Sunday, December 10, 2017 1:19:51 PM
Attachments: [image003.png](#)

Receipt of email acknowledged
Janice

Sent from my iPhone

On Dec 10, 2017, at 6:51 AM, Gildner, Jean <Jean.Gildner@fda.hhs.gov> wrote:

Dear Janice,

Please see the following information request. Please provide the information by COB **December 12, 2017**. Please acknowledge receipt of this email and confirm that you will be able to meet the requested deadline.

To the applicant

Please provide the thrombosis and thrombosis free rates for

<!--[if !supportLists]-->1) <!--[endif]-->Subjects exposed to andexanet

<!--[if !supportLists]-->2) <!--[endif]-->Subjects who received
prophylactic anticoagulation (for subjects who received
anticoagulation, please exclude subjects who developed a thrombotic
event before anticoagulation was initiated)

<!--[if !supportLists]-->3) <!--[endif]-->Subjects who did not receive
prophylactic anticoagulation (includes subjects for anticoagulation was
initiated after the event)

For the purposes of the requested analysis above, please note that AEDECOD
(provided by the applicant) has been revised or collated to the FDA term for
analyses purposes (see table below).

Please note for that for the purposes of analyses of thrombotic events, FDA
considered the following:

- Sudden death, embolism, venous or arterial thrombosis, infarction or infarct, cardiac failure, cardiogenic shock as thrombotic events.
In addition, the following events were re-adjudicated
- Subject (b) (6) – we have assessed the event termed basal ganglia hemorrhage as brain stem infarct as the narrative notes occurrence of brain stem infarct after the hemorrhagic event. Therefore this event is considered a thrombotic event.

- Subject (b) (6) – experienced a cardiac arrest and therefore included as experiencing a thrombotic event since myocardial infarction cannot be ruled out.
- Subject (b) (6) – experienced myocardial infarction prior to cardiogenic shock, therefore included as a thrombotic event.
- Subjects (b) (6) and (b) (6) experienced sudden deaths (one related to pulmonary embolism). All sudden deaths will be considered as thrombotic events unless clearly related solely to the hemorrhagic event.

<image009.jpg>

Jean F. Gildner MSHS, MT (ASCP)

Regulatory Project Manager
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[<image003.png>](#)

[<image004.jpg>](#) [<image005.jpg>](#) [<image006.jpg>](#) [<image007.jpg>](#)
[<image008.jpg>](#)

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