

From: [Janice Castillo](#)
 To: [Gildner, Jean](#)
 Subject: RE: BLA 125586 Information Request
 Date: Friday, February 09, 2018 5:31:49 PM
 Attachments: [image007.png](#)

IR received.
 Janice

From: Gildner, Jean [mailto:Jean.Gildner@fda.hhs.gov]
 Sent: Friday, February 09, 2018 11:29 AM
 To: Janice Castillo
 Subject: BLA 125586 Information Request

Dear Janice,

Please see the following information request. Please respond by Wednesday, February 14, 2018. Please acknowledge receipt of this email and that you will be able to meet the requested deadline.

Please use the collated terms that FDA has provided in the attached JMP table (please let me know that you got this attachment, too). It is recommended that you use JMP or SAS programs to open the file or you may need to save or convert to Excel to open. Please let me know if you have any difficulties.

A list of subject IDs of subjects who experienced any of the following events and referred to as FDA AESI suspicious for TEE (based on the FDA AE terms provided in the attachment): myocardial infarction, deep venous thrombosis, pulmonary embolism, ischemic or embolic or unknown reasons for a stroke, acute respiratory failure, congestive heart failure, cardiogenic shock, ventricular tachycardia, cardiac thrombus, cardiac arrest, or iliac artery occlusion.

A separate Subject ID list of subjects who experienced death (sudden, unwitnessed or death from any cause)

Analysis based on the summary table as provided:

Population	Bleed Type	No. of subjects not anticoagulation (n=)	No. of subjects who were anticoagulated (n=)		
			Total	Prior to event*	After the event*
Experienced FDA AESI events or death	All				
	ICH				
	GI				
	Other				
Did not experience FDA-AESI events or death	All				
	ICH				
	GI				
	Other				

Event* = Earliest onset of the FDA AESI event suspicious for TEE or death.

If you have any questions please feel free to contact me if you have any questions.

Sincerely, Jean

Jean F. Gildner MSHS, MT (ASCP)

Regulatory Project Manager
Center for Biologics Evaluation and Research
Office of Tissues and Advanced Therapies
U.S. Food and Drug Administration

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