

From: [Janice Castillo](#)
To: [Gildner, Jean](#)
Subject: RE: BLA 125586 Information Request
Date: Sunday, December 31, 2017 2:30:21 PM
Attachments: [image003.png](#)

Jean,
Receipt acknowledged I'll check with the team regarding the timeline for the response
Janice

From: Gildner, Jean [mailto:Jean.Gildner@fda.hhs.gov]
Sent: Sunday, December 31, 2017 10:55 AM
To: Janice Castillo
Subject: BLA 125586 Information Request

Dear Janice,

Please see the following information request Please respond by January 2, 2018 Please acknowledge receipt of this email and the ability to meet the deadline

Your response to the IR request of 12/21 is incomplete. The datasets (ADAE table) provided on 12/01/17 do not include the SAE events noted in Portola's IR response from 12/12/17. Therefore the discrepancies in the pdf document provided on 12/12/17 indicates that the ADAE data set of the 55 subjects provided on 12/01/17 underreports SAEs that is relevant to all 185 subjects in the ADL dataset. Therefore the ADAE dataset provided on 12/01/17 is incomplete, resulting in our inability to complete the review of the clinical data. As requested on the IR dated 12/21/17, Portola was notified that the following information was required, therefore

- 1) We repeat our request that Portola provide an updated ADAE dataset to include ALL adverse events for all 185 subjects as assessed by the INVESTIGATOR by 01/01/18, 12 noon EST

In addition to the above, based on the email response from 12/29/17, in order to confirm that the report of SAE in the ADAE data table from 12/01/17 was erroneous as you stated in this response, we request that you provide all hospitalization records, imaging reports for Subject (b) (6) as related to the study observation period for this subject. Please provide this response by 01/02/18 by 12 noon EST

The subject's ID is (b) (6), confirmed to have a DVT by the snap shot of the report provided here...

Venous Duplex LE Ltd Addl
* Final Report *

Result Type: Venous Duplex LE Ltd Addl
Result Date: (b) (6)
Result Status: Auth (Verified)
Result Title/Subject: Lower Limb Venous Duplex, Complete Bilateral
Encounter Info: WHC-00042877555, Washington Hosp, Inpatient, (b) (6)
Contributor system: WHC_VASCUBASE

* Final Report *

VL Venous Duplex LE Ltd Addl
Final Report

Department: Vascular Lab MWHC
Patient: (b) (6)
Account Number: (b) (6)
CPT Code: 93970
ICD-9:
ICD-10: R06.02

Impression
Bilateral lower extremities venous duplex revealed evidence to suggest non-occlusive DVT in the RT Peroneal veins and occlusive DVT in the LT Peroneal veins.

(b) (6) is an (b) (6) who was referred by (b) (6) for a Lower Limb Venous Duplex, Complete Bilateral on

Indications
Shortness of breath (R06.02), Thrombocytopenia D69.6, S/P CABG, HTN, DM, Afib
Admission Info Admission Date (b) (6)

However the ADAE dataset from 12/1 does not show the subject as listed. The screen shot from below does not include the subject in question (the dataset is ordered in sequence by ID#) in the ADAE dataset thereby we find the datasets to be discrepant and underreporting of the actual SAE events. Therefore we are requesting the request as listed as item 1 (We repeat our request that Portola provide an updated ADAE dataset to include ALL adverse events for all 185 subjects as assessed by the INVESTIGATOR by 01/01/18, 12 noon EST) in the email below

ADAE - JMP [5]											
File Edit Tables Rows Cols DOE Analyze Graph Tools Add-Ins View Window Help											
ADAE											
Notes: Adverse Events Analysis											
	STUDYID	USUBJID	SUBJID	SITEID	AGE	AGEU	AGEGRP	SEX	RACE	ETHNIC	ENRFL
1	14-505	14-505-	(b) (6)	001	74	YEARS	65 - 75 years	F	WHITE	NOT HISPANIC OR LATINO	Y
2	14-505	14-505-	(b) (6)	001	74	YEARS	65 - 75 years	F	WHITE	NOT HISPANIC OR LATINO	Y
3	14-505	14-505-	(b) (6)	002	81	YEARS	>75 years	F	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	Y
4	14-505	14-505-	(b) (6)	003	68	YEARS	65 - 75 years	F	WHITE	NOT HISPANIC OR LATINO	Y
5	14-505	14-505-	(b) (6)	003	74	YEARS	65 - 75 years	M	WHITE	NOT HISPANIC OR LATINO	Y
6	14-505	14-505-	(b) (6)	004	60	YEARS	<65 years	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	Y
7	14-505	14-505-	(b) (6)	004	79	YEARS	>75 years	M	WHITE	UNKNOWN	Y

In addition please provide EAC adjudication reports for each of each of the subjects. You have submitted blank EAC report forms in your response dated December 29, 2017

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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