

From: Maruna, Thomas
Sent: Wednesday, March 23, 2016 10:48 AM
To: 'Denloye, Aderonke O'
Subject: March 23. 2016 (Clinical) Information Request - BLA 125596.0 - Please Respond by March 30. 2016

Importance: High

Baxalta US Inc.
Attention: Ms. Aderonke Denloye
March 23, 2016
Sent by email

Dear Ms. Denloye:

We are reviewing your September 14, 2015 biologics license application (BLA) to treat primary immune deficiency disorders associated with defects in humoral immunity for the following:

STN	Name of Biological Products
125596/0	Immune Globulin Subcutaneous (Human), 20% Solution

We have determined the following information is required to continue our review:

1. Please indicate the annualized rate of related TEAEs per subject and per infusion for the KIOVIG cohort.
2. Please complete the blank spaces for Percent of Subjects, Number of Subjects, Rate per Subject, and Rate per Infusion, in the table of TEAEs, below.

Preferred Term	Product	Percent of Subjects	Number of Subjects	Rate per Subject	Rate per Infusion
Headache					
	KIOVIG				
	SUBCUVIA				
	Cuvitru				
Infusion site erythema					
	SUBCUVIA				
	Cuvitru				
Infusion site pain					
	SUBCUVIA				
	Cuvitru				
Injection site pain					
	SUBCUVIA				
	Cuvitru				
Injection site					

discomfort	SUBCUVIA				
	Cuvitru				
Infusion site pruritus					
	SUBCUVIA				
	Cuvitru				
Infusion site swelling					
	SUBCUVIA				
	Cuvitru				

3. Please verify the accuracy of the data included in the following table of related TEAEs.

Parameter	KIOVIG	SUBCUVIA	Cuvitru
Systemic TEAEs			
Annualized rate per subject	2.9	2.7	1.6
Rate of TEAEs per infusion	0.2	0.6	0
Local TEAEs			
Annualized rate of TEAEs per subject	0	0.3	3.6
Rate of TEAEs per infusion	0	0.0	0.7
Infusional TEAEs			
Annualized rate of TEAEs per subject	1.3	1.9	9.5
Rate of TEAEs per infusion	0.3	0.2	0.2

Please submit your responses as an amendment to this file by March 30, 2016 referencing the date of this request.

The review of this submission is on-going and issues may be added, expanded upon, or modified as we continue to review this submission.

The action due date for these files is September 13, 2016.

Very Respectfully,

Thomas J. Maruna, MSc, MLS(ASCP), CPH

Lieutenant, U.S. Public Health Service

Senior Regulatory Management Officer

Food and Drug Administration

Center for Biologics Evaluation and Research

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