

From: Maruna, Thomas
Sent: Thursday, March 10, 2016 10:51 AM
To: 'Denloye, Aderonke O'
Subject: March 10. 2016 (Clinical) Information Request - BLA 125596.0 - Please Respond by March 17. 2016

Importance: High

Baxalta US Inc.
Attention: Ms. Aderonke Denloye
March 10, 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 where Appendix 16 is located in the 3 clinical study reports for studies 160601, 170903, and 170904.
2. Please clarify why subject (b) (6) (study 170904) was terminated for "non-compliance".

Please submit your responses as an amendment to this file by March 17, 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,

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