

**From:** Maruna, Thomas  
**Sent:** Monday, April 11, 2016 10:46 AM  
**To:** 'Denloye, Aderonke O'  
**Subject:** April 11. 2016 (Clinical) Information Request - BLA 125596.0 - Please Respond by April 22. 2016

**Importance:** High

Baxalta US Inc.  
Attention: Ms. Aderonke Denloye  
April 11, 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:

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

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

1. With respect to the PI (prescribing information), please submit an amended draft version that includes data from Study 170903 for (a) Table 3, 4 and 7 and (b) Section 6.1 and 14.

Please submit your responses as an amendment to this file by April 22, 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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