

**From:** Maruna, Thomas  
**Sent:** Monday, February 22, 2016 1:59 PM  
**To:** 'Denloye, Aderonke O'  
**Cc:** Storch, Emily  
**Subject:** February 22. 2016 Information Request - BLA 125596.0 - Please Respond by February 29. 2016

**Importance:** High

Baxalta US Inc.  
Attention: Ms. Aderonke Denloye  
February 22, 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. In Table 20, "Proportion of Infection which Resolved/Continued in the Course of the Study", Full Clinical Study Report 170904 you list 8 unresolved infections in the Cuvitru group. Please submit any updated information you have on these 8 subjects as to whether their infections have since resolved.

Please submit your responses as an amendment to this file by February 29, 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  
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Senior Regulatory Management Officer  
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