

**From:** Maruna, Thomas  
**Sent:** Tuesday, May 03, 2016 12:04 PM  
**To:** 'Denloye, Aderonke O'  
**Subject:** May 3. 2016 Information Request - BLA 125596.0 - Please Respond by May 10. 2016

**Importance:** High

Baxalta US Inc.  
Attention: Ms. Aderonke Denloye  
May 3, 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:

We have reviewed your validation reports (STN 125596) submitted in amendment 5 dated Feb. 3, 2016 and amendment 16, dated Mar. 30, 2016. We have the following information request.

1. You have not provided acceptable response to our question 1a in amendment 5. That your results met specification, do not justify that your results did not have to meet your internal acceptance criteria for precision (repeatability and intermediate precision). Based on your results, we feel that your validation studies failed to demonstrate adequate repeatability and intermediate precision of the assay. Please explain why your results did not meet your internal acceptance criteria and provide data to show that your results could meet your internal acceptance criteria consistently.
2. You determined LOQ by (b) (4)



(b) (4) using the equation  $LOQ = 10\sigma/S$  as described in ICH Q2(R1). Please reevaluate the LOQ and submit results for review.

3. You performed (b) (4) of spiking experiment using a (b) (4) IGSC 20% sample on a normal IGSC 20% sample for accuracy study in the validation report PV-LA-16.004. But the recoveries are not calculated and thus the results are inconclusive for the accuracy of the method. Please calculate the recoveries for each molecular species and submit for review.

Please submit your responses as an amendment to this file by May 10, 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

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