

**From:** Kelly, Sunday  
**Sent:** Monday, April 25, 2016 3:38 PM  
**To:** angela.blackshere@baxalta.com  
**Cc:** Maruna, Thomas (Thomas.Maruna@fda.hhs.gov)  
**Subject:** Postmarketing Commitment Request - BL 125596/0 - Immune Globulin Subcutaneous (Human), 20% Solution  
**Importance:** High

*Sent on behalf of LT Thomas Maruna*

Our Reference: BL 125596/0  
Baxalta US, Inc.  
Attention: Ms. Angela Blackshere  
April 25, 2016  
Sent by email

Dear Ms. Blackshere:

We are reviewing your September 14, 2015, BLA for Immune Globulin Subcutaneous (Human), 20% Solution. We request that you make the following postmarketing commitments:

1. Based on one year of manufacturing experience, please establish specifications for (b) (4), osmolality, (b) (4), and (b) (4) for IGSC, 20% final product. Validation of tests, proposed specifications, and testing data will be submitted as a PAS by July 13, 2017. In the meantime, you may modify your Lot Release Protocol by adding these tests "For Information."
2. Please calibrate the (b) (4) assay using the (b) (4) international standard, with results reported as mIU (b) (4). In the meantime, you may modify your Lot Release Protocol by adding the (b) (4) "For Information." The recalibrated assay, and a proposed lot release specification based on manufacturing experience, will be submitted as a PAS by September 13, 2017.

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

Please submit your response as an amendment to this file referencing the date of this request.

The action due date for this file is September 13, 2016.

If you have any questions this week, please contact me.

Sincerely,

**Sunday L. Kelly, MS, RAC, PMP**

Regulatory Project Manager  
U.S. Food & Drug Administration  
Center for Biologics Evaluation and Research  
Office of Blood Research and Review  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002  
Voice# 240.402.8410  
Mobile# 240.507.8446  
Fax# 301.595.1128

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