

From: Kelly, Sondag
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,

Sondag L. Kelly, MS, RAC, PMP

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