

From: Maruna, Thomas
Sent: Tuesday, August 09, 2016 11:36 AM
To: 'Denloye, Aderonke O'
Cc: Reed, Jennifer; Wang, Hsiaoling
Subject: 09-Aug-2016 Information Request - BLA 125596.0 - Please Respond by 12-Aug-2016

Importance: High

Baxalta US Inc.
Attention: Ms. Aderonke Denloye
August 9, 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:

| STN | Name of Biological Products |
|----------|--|
| 125596/0 | Immune Globulin Subcutaneous (Human), 20% Solution |

Please promptly submit your written response to the following items so that we may continue evaluating your BLA:

1. After reviewing of the response you submitted in the amendment 32, dated July 31, 2016, we found that evaluation of linearity is inappropriate in the validation report (DP-99-00304) of "Purity determination and (b) (4) quantification in IGIV products by (b) (4)". A plot of measured purity% against expected purity% provides the evaluation for accuracy, not linearity. Please provide (b) (4) to demonstrate linearity of your assay.

Please submit your response by **August 12, 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
Center for Biologics Evaluation and Research
Office of Blood Research and Review
10903 New Hampshire Ave.
Silver Spring, MD 20993
thomas.maruna@fda.hhs.gov
O: (240) 402-8454
www.usphs.gov



"THIS MESSAGE, INCLUDING ANY ATTACHMENTS, IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.