

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

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