

From: Maruna, Thomas
Sent: Tuesday, May 03, 2016 12:34 PM
To: 'Denloye, Aderonke O'
Subject: May 3. 2016 (Clinical) Information Request - BLA 125596.0 - Please Respond by May 6. 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:

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

We have determined the following information is required to continue our review:

1. Please specify the Integrated Summary of Safety Table number(s) from which the data for Table 3 and Table 4 in the PI were obtained.
2. For study 160601, please draft a table of nonserious adverse events by absolute number of subjects (as opposed to proportion of subjects). This table should have
(a) 6 columns labeled Classification, Part 1, Part 2, Part 3a, Part 3b and Extension (with appropriate sample size for each) and (b) 2 rows labeled local adverse reactions and systemic adverse reactions. The number of subjects, Preferred Term (where applicable), and severity of each adverse reaction in each study Part should be limited to an incidence \geq 5%.

Please submit your responses as an amendment to this file by May 6, 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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