

From: Maruna, Thomas
Sent: Friday, July 15, 2016 11:14 AM
To: 'Denloye, Aderonke O'
Cc: Landow, Laurence; Reed, Jennifer
Subject: 15-July-2016 Information Request - BLA 125596.0 - Please Respond by 22-July-2016

Importance: High

Baxalta US Inc.
Attention: Ms. Aderonke Denloye
July 15, 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

The following information is required to continue our review:

1. Please submit safety data in tabular format (similar to the tables referenced in the 7/5/2016 email from Aderonke) for the comparators used in studies 170904 and 170903 with respect to individual local and systemic adverse reactions that occurred at an incidence $\geq 5\%$ and were causally related and/or temporally associated.
2. Please also submit a revised table of pooled local and systemic adverse reactions in both studies that occurred at an incidence $\geq 5\%$ and were causally related and/or temporally associated.

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 responses as an amendment to this file by July 22, 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

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