

From: Maruna, Thomas
Sent: Thursday, February 25, 2016 11:34 AM
To: 'Denloye, Aderonke O'
Subject: February 25. 2016 Information Request - BLA 125596.0 - Please Respond by March 3. 2016

Importance: High

Baxalta US Inc.
Attention: Ms. Aderonke Denloye
February 25, 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. Applicants should provide the software programs used to create all ADaM datasets along with the tables and figures associated with primary and secondary efficacy analyses in order to help reviewers to better understand how the datasets, tables and figures were created.

There are 3 studies in your BLA in total. One study contains SAS program while other two studies have no SAS program; study 160601 contains the SAS program. Please submit an SAS program for studies 170903 and 170904.

Please submit your responses as an amendment to this file by March 3, 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

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