

From: Maruna, Thomas
Sent: Monday, April 11, 2016 10:46 AM
To: 'Denloye, Aderonke O'
Subject: April 11. 2016 (Clinical) Information Request - BLA 125596.0 - Please Respond by April 22. 2016

Importance: High

Baxalta US Inc.
Attention: Ms. Aderonke Denloye
April 11, 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. With respect to the PI (prescribing information), please submit an amended draft version that includes data from Study 170903 for (a) Table 3, 4 and 7 and (b) Section 6.1 and 14.

Please submit your responses as an amendment to this file by April 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
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



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