

From: Maruna, Thomas
Sent: Monday, June 13, 2016 10:16 AM
To: 'Denloye, Aderonke O'
Cc: Campbell, Karen M; Reed, Jennifer
Subject: 13-June-2016 Information Request - BLA 125596.0 - Please Respond by 30-June-2016

Importance: High

Baxalta US Inc.
Attention: Ms. Aderonke Denloye
June 13, 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 IR concerns the LRP template submitted in amendment 125596/0.24 on May 31, 2016.

1. On page 3 of 5, in the sterility template, please confirm that the specification will be No growth and please state the result as growth or no growth.
2. On page 5 of 5, the signature is not needed

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 June 30, 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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