

From: Maruna, Thomas
Sent: Tuesday, June 14, 2016 2:27 PM
To: 'Denloye, Aderonke O'
Cc: Reed, Jennifer; Landow, Laurence
Subject: 14-Jun-2016 (Clinical) Information Request - BLA 125596.0 - Please Respond by 21-Jun-2016

Importance: High

Baxalta US Inc.
Attention: Ms. Aderonke Denloye
June 14, 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 (a) calculate the point estimate and confidence interval for Serious Bacterial Infections in pediatric subjects aged 2 to <16 years in Study 170904 and Study 170903 and (b) provide the statistical software package used to compute these numbers.

Please submit your responses as an amendment to this file by June 21, 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,

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