

From: Maruna, Thomas
Sent: Thursday, March 10, 2016 10:01 AM
To: 'Denloye, Aderonke O'
Subject: March 10. 2016 Information Request - BLA 125596.0 - Please Respond by March 24. 2016

Importance: High

Baxalta US Inc.
Attention: Ms. Aderonke Denloye
March 10, 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 provide concentration-time data for total IgG following SC administration for pediatrics (0-<6 and 6 to 12 years of age). Please show the method for the estimation of PK parameters.

In order to compare the pediatric PK with adults, select the same time points as of aforementioned pediatric age groups from adults and estimate the PK parameters in adults. Method for the estimation of PK parameters should be similar for children and adults.

2. In a tabulated form, please provide each subject's age, body weight, gender, ethnicity, and dose.

Please submit your responses as an amendment to this file by March 24, 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

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