

From: Maruna, Thomas
Sent: Friday, December 04, 2015 1:40 PM
To: 'Denloye, Aderonke O'
Subject: December 4. 2015 Information Request (CMC) - Baxalta - STN 125596.0 - Please Respond by December 18. 2015

Baxalta US Inc.
Attention: Ms. Aderonke Denloye
December 4, 2015
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. Study IGSC_1-SD-11-B-SR alludes to interim stability data supporting (b) (4) of IGSC 20%. However these data appear to be missing from the stability report 99911-CMC-006.US. Please provide the data set.

Please submit your responses to question 1 as an amendment to this file by December 18, 2015 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.

If you have any questions, please contact me.

Very Respectfully,

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