

From: Kelly, Sunday
To: [Denloye, Aderonke O \(Ade_Denloye@baxter.com\)](mailto:Denloye_Aderonke_O (Ade_Denloye@baxter.com))
Subject: FDA Request for Info - Immune Globulin Subcutaneous (Human), 20% Solution - BL 125596/0 - Study 170903, Appendix 16.2.7
Date: Wednesday, July 20, 2016 1:00:00 PM
Importance: High

Sent on behalf of LT Thomas Maruna

Our Reference: BL 125596/0

Baxalta US, Inc.
Attention: Ms. Aderonke Denloye
July 20, 2016
Sent by email

Dear Ms. Denloye:

We are reviewing your September 14, 2015 BLA for Immune Globulin Subcutaneous (Human), 20% Solution to treat primary immune deficiency disorders associated with defects in humoral immunity.

We determined that the following information is necessary to continue our review:

1. For subject **(b) (6)** in study 170903, please clarify the following discrepancy:
 - Page 694/737 of the CSR states subject **(b) (6)** was born in 2001.
 - Adverse Event Listings 5, 35 and 36 list the subject's age as 9 years. Since study 170903 began enrollment on 20 June 2011, how could he be 9 years of age?

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 response to this information request as an amendment to this file by to this file *ASAP* referencing the date of this request.
The action due date for this file is September 13, 2016.

If you have any questions this week, please contact me.

Sincerely,
Sunday L. Kelly, MS, RAC, PMP

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