

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 170904
Date: Friday, July 22, 2016 1:15:00 PM
Importance: High

Sent on behalf of LT Thomas Maruna

Our Reference: BL 125596/0

Baxalta US, Inc.
Attention: Ms. Aderonke Denloye
July 22, 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. In Table 3, page 20 of 48 in the ISE, please clarify the number of 170904 subjects who were White, Black or African American, Hispanic, Asian and Multiple. The number appears to total 82 but the total number of enrolled subjects is listed as 77.

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.

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

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