

From: Kelly, Sunday
To: [Denloye, Aderonke O \(Ade.Denloye@baxter.com\)](mailto:Denloye.Aderonke.O (Ade.Denloye@baxter.com))
Cc: [Maruna, Thomas \(Thomas.Maruna@fda.hhs.gov\)](mailto:Maruna.Thomas (Thomas.Maruna@fda.hhs.gov))
Subject: FDA Request for Info - Immune Globulin Subcutaneous (Human), 20% Solution - BL 125596/0
Date: Wednesday, July 20, 2016 12:49:00 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 the “Purity by (b) (4) ” assay (CTP LE-13-A05001), you have demonstrated the specificity and precision in your validation report. Please provide accuracy, linearity, and range data to complete a full validation for this quantitative method.

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. Please let us know when you would be able to provide the final validation report.

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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