

From: Kelly, Sunday
To: [Denloye, Aderonke O \(Ade_Denloye@baxter.com\)](mailto:Denloye.Aderonke.O@baxter.com)
Cc: [Maruna, Thomas \(Thomas.Maruna@fda.hhs.gov\)](mailto:Maruna.Thomas@fda.hhs.gov)
Subject: FDA Request for Info - Immune Globulin Subcutaneous (Human), 20% Solution - BL 125596/0 - Listing 30, Study 170903
Date: Thursday, July 21, 2016 1:32:00 PM
Importance: High

Sent on behalf of LT Thomas Maruna

Our Reference: BL 125596/0

Baxalta US, Inc.
Attention: Ms. Aderonke Denloye
July 21, 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. Please clarify what abbreviations "SCV" and "IVSCV" in Listing 30, Appendix 16.2.7 of study 170903 stand for.

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 by email *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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