

From: Maruna, Thomas
Sent: Tuesday, October 20, 2015 1:45 PM
To: ade.denloye@baxalta.com
Subject: 10-20-2015 Information Request - BLA 125596.0 - Please Respond by October 28. 2015

Importance: High

Baxalta US Inc.
Attention: Ms. Aderonke Denloye
October 20, 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 determined that the following information is necessary to continue our review:

1. Per 21 CFR 54.4(a)(1) and (3), please submit financial disclosure forms FDA 3454 and/or 3455 with authorized signature (*signed by the APPLICANT, not an Agent*).
2. Please submit the coding dictionary used for mapping investigator verbatim terms to preferred terms.

If these documents and information have been submitted to the BLA, please respond to this email referencing their location. If they have not been submitted, please submit your responses as an amendment to this file by October 28, 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,

Thomas J. Maruna, MSc, MLS(ASCP)^{CM}
Lieutenant, U.S. Public Health Service
Senior Regulatory Management Officer
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Center for Biologics Evaluation and Research

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