

From: Thompson, Edward
Sent: Tuesday, June 21, 2016 1:40 PM
To: 'ade.denloye@shire.com'
Cc: 'angela.blackshere@shire.com'; Maruna, Thomas
Subject: Information Request for BL 125596/0

Baxalta US Inc.
Attention: Ms. Aderonke Denloye
June 21, 2016
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 have reviewed your analytical procedures and validation of analytical procedures for “(b) (4) [REDACTED] of Gammagard S/D, Gammagard Liquid/Kiovig and IGSV 20% Product by (b) (4)” and we request that you review and submit a revised package insert label:



Please submit your responses to as an amendment by July 5, 2016. Please include both a red-line strike out and clean copy of the revised package insert in WORD format.

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 an acknowledgement message for receipt of this request.

The action due date for these files is September 13, 2016.

If you have any questions, please contact Thomas Maruna at (240) 402-8454.

Edward Thompson
Regulatory Project Manager
FDA/CBER

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