

From: Maruna, Thomas
Sent: Monday, November 30, 2015 11:34 AM
To: 'Denloye, Aderonke O'
Subject: November 30. 2015 Information Request - BLA 125596.0 - Please Respond by December 12. 2015

Importance: High

Baxalta US Inc.
Attention: Ms. Aderonke Denloye
November 30, 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 have reviewed your analytical procedures and validation of analytical procedures for “(b) (4) of Gammagard S/D, Gammagard Liquid/Kiovig and IGSV 20% Product by (b) (4)” and we have following information request:

1. Method (Doc ID: LE-13-A04001-CTP00)
 - Please confirm that no (b) (4) is used for the IGSC 20% sample before (b) (4) in section 4.2
 - Please specify the (b) (4) method for (b) (4) in section 5
 - Please specify the (b) (4) during the (b) (4)
 - Please provide details of (b) (4) in section 3.4
2. Validation (Doc ID: LE-65-A04001S/01 and PV-LA-09.007)

The (b) (4) is identified as a compendial method ((b) (4)) in the submission. In your validation report, only the precision is evaluated. The (b) (4) assay is a critical assay directly related to the safety of this product. Therefore, a full validation of the method is necessary, which means it should be validated as a quantitative method for the (b) (4) and as a quantitative impurity test for the (b) (4) as well as for the (b) (4) and address necessary validation characteristics, including specificity, linearity, precision, accuracy, and for the impurities also LOQ.

Please submit your responses to question 1 as an amendment to this file by Decembert 12, 2015 referencing the date of this request; please provide a timeline for question 2.

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

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