

From: Maruna, Thomas
Sent: Wednesday, February 10, 2016 12:25 PM
To: 'Denloye, Aderonke O'
Subject: Sample and Reagent Request for BLA 125596.0 - Please Respond By February 25. 2016

Importance: High

Baxalta US Inc.
Attention: Ms. Aderonke Denloye
February 10, 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 determined the following is required to continue our review:

1. Please provide 1 vial per lot, of any lots that have been produced that are intended for distribution after approval. If three lots are not available please notify CBER and we can discuss lots that can be sent for in-support testing.

Each lot intended for distribution should be accompanied by a concurrent testing letter, to be followed by the lot release protocol, once we have indicated that the lot release protocol template submitted in the BLA is acceptable for use.

Please ship samples to:

Food and Drug Administration
Center for Biologics Evaluation and Research
Sample Custodian
10903 New Hampshire Avenue
WO75-G707
Silver Spring, MD 20993-0002

2. Please provide BRP reference standard (2 vials of 150 microliter with description of dilution status and storage condition).
3. Please provide the injection sequence for one set of (b) (4), including (b) (4), sample, etc. because it is not described in

the SOP, LE-13-A04001-CTP00. This may be sent by e-mail to the RPM, Thomas Maruna.

4. Please provide the test results of the drug product lots submitted, if they have not already been submitted to the BLA.

Ship reagents to the address listed below:

Alfred Del Grosso

Laboratory of Analytical Chemistry Team Lead
Food and Drug Administration
Center for Biological Evaluation and Research
Division of Biological Standards and Quality Control
10903 New Hampshire Avenue
WO75, G-717
Silver Spring, MD 20993-0002

Please send samples and reagents for receipt by February 25, 2016 and contact us when the shipments have been sent. Please contact us if this is not feasible.

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), CPH

Lieutenant, U.S. Public Health Service
Senior Regulatory Management Officer
Food and Drug Administration
Center for Biologics Evaluation and Research
Office of Blood Research and Review
10903 New Hampshire Ave.
Silver Spring, MD 20993
thomas.maruna@fda.hhs.gov
O: (240) 402-8454
www.usphs.gov



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