

From: Kelly, Sunday
Sent: Monday, April 25, 2016 3:28 PM
To: 'angela.blackshere@baxalta.com'
Cc: Maruna, Thomas (Thomas.Maruna@fda.hhs.gov); 'ade.denloye@baxalta.com'
Subject: FDA Request for Information - Lot Release Protocol Template Review - BL 125596/0 - Immune Globulin Subcutaneous (Human), 20% Solution (Please Respond by May 16, 2016)
Importance: High

Sent on behalf of LT Thomas Maruna

Our Reference: BL 125596/0
Baxalta US, Inc.
Attention: Ms. Angela Blackshere
April 25, 2016
Sent by email

Dear Ms. Blackshere:

We are reviewing your October 14, 2016, Lot Release Protocol Template submission to your BLA for Immune Globulin Subcutaneous (Human), 20% Solution.

We are providing the following comments and request for additional information to continue our review:

1. On each page, in the header, the CC line is missing from the protocol. It must be at the top of the each page and in the following format “cc: STN#-0/license #/product type (FC, B, etc.)”
2. On page 2 of 4, please include the date test completed for each of the tests.
3. On page 2 of 2, please include the (b) (4) Assay, including the results (in U/ml) and the specifications (b) (4) for the test.
4. On page 4 of 4 for Sterility, please add additional information. Please see the attached example of a suggested template for this information.
 - a. Please add the (b) (4) test date, above the table
 - b. The Type of sample (i.e., bulk, final container) above the table
 - c. The quantities tested per media type (as part of the table)
 - d. Result (pass/fail) below the table
 - e. Specification (b) (4) below the table
5. Please include more information on the Bacterial Endotoxins test performed. Please see the attached example of a suggested template for this information.

Sterility

Method used: _____

Type: *for example, Viral Harvests, Bulk, Final Container*

B&F Test Date: _____

On Test Date	Medium/Temperature	Tested Quantity	Off Test Date

Result:

Specification:

Lot Number:

License Name of Product

(b) (4)

(b) (4)

Test date _____

Name of (b) (4) Manufacturer _____

(b) (4) Lot number _____

Standard Curve Information

Endotoxin lot number _____

Endotoxin Mfr/Supplier _____

Standard Curve (performed for each analytical session)

	Standard Endotoxin Concentration IU/mL	Mean Onset Time (seconds)	CV%
1			
2			
3			
4			
5			
6			

Correlation coefficient (r): _____ Intercept: _____ Slope: _____

Product Test Summary

MVD _____

	Results IU/mL	Test Dilution	Mean Onset Time	CV%	% Spike Recovery
Beginning					
Middle					
End					

Results (IU/mL): _____

Specifications:

Calculations or additional comments

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 as an amendment to this file by to this file by May 16, 2016, 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,

Sonday L. Kelly, MS, RAC, PMP

Regulatory Project Manager
U.S. Food & Drug Administration
Center for Biologics Evaluation and Research
Office of Blood Research and Review
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Voice# 240.402.8410
Mobile# 240.507.8446
Fax# 301.595.1128

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please notify the sender immediately by e-mail or phone.