

From: [Do, Yu](#)
To: [James Maloney](#)
Subject: Information Request (Response Due by Thursday, March 14, 2019): Class 2 Resubmission, BL 125590/0, Immune Globulin Intravenous (Human), 10% Liquid, ADMA Biologics, Inc.
Date: Monday, March 04, 2019 9:13:00 AM
Attachments: [image001.png](#)
Importance: High

Dear Mr. Maloney:

We are reviewing your resubmission of September 28, 2018, to BL 125590/0 for Immune Globulin Intravenous (Human), 10% Liquid. We determined that the following information is necessary to continue our review:

We have reviewed your response to our Information Request dated February 12, 2019, regarding the assay for (b) (4) Test Method for 101801 DP (b) (4) (TM-10058) and have additional requests for information:

Assay for (b) (4)

- a. Please provide a summary of the differences between (b) (4) Assay Test Method for Biotest Pharmaceuticals Immune Globulin Drug Product (TM-10011) and the (b) (4) Test Method 101801 IVIG DP (b) (4) (TM-10058).
- b. In the Amendment 51 to BL 125590/0, Response to FDA Request for Information, dated February 22, 2019, you reported linearity by (b) (4).
Linearity should be determined by (b) (4).
Please submit your linearity results from plots of response vs. activity for both standard and sample, and evaluation of parallelism between the standard and sample dilution curves for the (b) (4) Test Method 101801 IVIG DP (b) (4) (TM-10058).
- c. The LOQ is the lowest point at which an analyte in a sample can be quantitatively determined with adequate precision and accuracy. In your assessment of LOQ you reported the activity of the lowest level (b) (4) of the reference standard curve which met the criteria for accuracy and precision as your LOQ. However, LOQ determination should include analysis of the drug product, as you are measuring the activity in the drug product. Please provide accuracy and precision results from the evaluations of the drug product (DP) to demonstrate that the (b) (4) method can adequately measure DP at (b) (4).
- d. In the assessment of the range of the method, you presented your reported LOQ as the lowest point of your assay range. While your approach is acceptable, please reevaluate the range of your method if the assessment of LOQ of your (b) (4) method for the drug product, as requested above, results in a different LOQ.

The review of this submission is ongoing, and issues may be added, expanded upon, or modified as we continue to review this submission. Please submit your response as an amendment to this file (BL 125590/0) by March 14, 2019, referencing the date of this request. If you anticipate you will not be able to respond by this date, please contact the Agency immediately so a new response date can be identified.

If we determine that your response to this information request constitutes a major amendment, we will notify you in writing.

The action due date for this file is April 2, 2019.

Please acknowledge receipt of this request and contact me at (240) 402-8343 or Yu.Do@fda.hhs.gov if you have any questions.

Sincerely,

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