



Our Reference: BLA 125668/o

Octapharma Pharmazeutika Produktionsges.m.b.H.  
Attention: Mr. Stanley Ammons  
November 21, 2018  
Sent by email

Dear Mr. Ammons:

We are reviewing your December 28, 2017, biologics license application (BLA), for Immune Globulin Subcutaneous (Human). We have the following request for information regarding the validation reports of the analytical procedures “Total Protein Determination” and “(b) (4) [REDACTED] for Molecular Size Distribution:”

1. Total Protein Determination

Please provide a linearity evaluation using your standard ((b) (4) [REDACTED]) and statistical analysis of data obtained from the standard and the drug product (CUTAQUIG) to demonstrate parallelism between the standard and the drug product.

2. (b) (4) [REDACTED] for Molecular Size Distribution

We are concerned that you did not provide evidence that the aggregates were not (b) (4) [REDACTED]. Please provide appropriate data to show that there is no (b) (4) [REDACTED] of aggregates on the (b) (4) [REDACTED] under the assay condition

The review of this submission is on-going and issues may be added, expanded upon, or modified.

Please submit your response to this information request as an amendment to this file by December 4, 2018, referencing the date of this request.

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 December 29, 2018.

Please send an email message acknowledging receipt of this request.

If you have any questions, please contact me.

Sincerely,  
Edward Thompson  
Regulatory Project Manager  
FDA/CBER/OTAT/DRPM

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Thank you