



Our Reference: BLA 125668/o

Octapharma Pharmazeutika Produktionsges.m.b.H.

Attention: Mr. Stanley Ammons

July 24, 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 regarding the validation report of the analytical procedure “Determination of Sodium in Cutaquig Final Container Samples by (b) (4)” (138VAL029FC 81x):

In the response to our May 22, 2018 requests in the amendment 10 (dated June 7, 2018), you stated that your instrument output for the sodium measurement was already in the unit of sodium concentration. Thus, the linear plots of the instrumental response versus sodium concentration are not available. While your explanation is acceptable to us, we note that your linearity and LOQ assessments include data points that are below LOQ, which is not acceptable. Please remove the data points below the LOQ and reevaluate the linearity and LOQ in the validation report. Make necessary change in your report and conclusion accordingly and submit for review.

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 August 7, 2018, 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 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