



Our Reference: BLA 125668/o

Octapharma Pharmazeutika Produktionsges.m.b.H.

Attention: Mr. Stanley Ammons

October 16, 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 comments and request for your information on bioanalytical method validation for analytes in clinical study SCGAM-01:

Per your IR response submitted on August 23, 2018, you requested to keep the mentioning of the (b) (4) and more frequently than weekly dosing in labeling based on your population PK (PopPK) analysis. However, you did not submit the PopPK study report.

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 October 23, 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