



Our Reference: BLA 125668/o

Octapharma Pharmazeutika Produktionsges.m.b.H.

Attention: Mr. Stanley Ammons

May 29, 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 amendment for your response to the information request submitted on 02/07/2018, you referred to updated section 16.1.10.1.2 (Module 5, section 5.3.5.2. Study SCGAM-01) for bioanalytical method validation information. However, you only provided a summary table with intra-assay, inter-assay precision and accuracy data. This is not adequate. Per FDA Guidance to Industry - Bioanalytical Method Validation (posted May 2018, <https://www.fda.gov/downloads/Drugs/Guidance/ucm070107.pdf>), bioanalytical method validation should include information of 1) reference standards and critical reagents, 2) calibration curve, 3) quality control samples, 4) selectivity and specificity, 5) sensitivity, 6) accuracy, precision and recovery, and 7) stability. Please refer to above mentioned guidance and submit updated bioanalytical method validation report for analytes in your clinical study SCGAM-01.

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 June 12, 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/OBRR/RPMS