



Our Reference: BLA 125668/o

Octapharma Pharmazeutika Produktionsges.m.b.H.

Attention: Mr. Stanley Ammons

June 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 determined that the following information is necessary to continue our review:

Please verify the one-sided 95% one-sided CI Upper limit for the number of “other infections” per subject as listed in Table 9 (page 66 of 3029) of the clinical study report for Phase 3 study SCGAM-01 using SAS proc Genmod or Glimmix.

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 July 6, 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/OBRR/RPMS