



Our Reference: BLA 125668/o

Octapharma Pharmazeutika Produktionsges.m.b.H.

Attention: Mr. Stanley Ammons

August 10, 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:

1. Please provide stand-alone programs (no macros used) for all variables in Table 9 (page 66 of 3029) of the clinical study report for Phase 3 study SCGAM-01 (excluding already submitted stand-alone programs for upper confidence limits of other infections).
2. Please provide the stand-alone programs for the upper bound of the 1-sided 99% CI for the primary endpoint, serious bacterial infections, and descriptive statistics for the following secondary efficacy endpoints:
  - a. Annual rate of all infections regardless of seriousness
  - b. Hospitalizations due to infection (number of days and annual rate)

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 20, 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

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Thank you