



Our Reference: BLA 125668/o

Octapharma Pharmazeutika Produktionsges.m.b.H.

Attention: Mr. Stanley Ammons

August 27, 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. The 120-day safety update reports six SAEs in extension study SCGAM-03, including 2 episodes of status asthmaticus in one subject. Please submit a detailed narrative of the status asthmaticus SAEs, including information on the timing of the onset of the SAEs in relation to the start and end times of the most recent investigational product SC infusions.
2. Please submit a detailed narrative for the AE in study SCGAM-03 consisting of cellulitis of abdominal wall, considered related by investigator/sponsor.
3. Please submit the final study report for completed non-IND Russian study SCGAM-04, which you indicated in the safety update is available upon request.
4. Please submit the final protocol and a summary of all protocol amendments for study SCGAM-04. These appear to be missing from the IND amendment that was to contain them in response to an earlier information request.

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 30, 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.