



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 and your inquiry on October 24, 2018 on the pediatric study plan:

1. We do not agree with your proposal.
2. Please do not submit a further revised PSP.
3. We expect the following minimum number of subjects by age stratum to have PK data in the final study report:
 - a. Age 2 to < 6 years: 2 subjects
 - b. Age 6 to < 12 years: 6 subjects
 - c. Age 12 to < 17 years: 4 subjects
 - d. Please do not specify a maximum number of subjects in any pediatric age category.
4. Please provide PREA PMR calendar date milestones (not calendar quarters) for:
 - a. final protocol submission
 - b. Study completion
 - c. Final report submission

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 November 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/OTAT/BII

THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW

If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by telephone and return it to us at the above address by mail.

Thank you