



Our Reference: BLA 125668/o

Octapharma Pharmazeutika Produktionsges.m.b.H.

Attention: Mr. Stanley Ammons

December 7, 2018

Sent by email

Dear Mr. Ammons:

We are reviewing your December 28, 2017, biologics license application (BLA), for Immune Globulin Subcutaneous (Human). We are providing comments and request for additional revisions with your prescribing information (PI) label:

1. Please include the revisions found in the attached FDA revised PI label.

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 December 10, 2018, referencing the date of this request. Please include both a **red-line strike out and clean copy** of the revised package insert in WORD format. 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/DRPM