



Our Reference: BLA 125668/o

Octapharma Pharmazeutika Produktionsges.m.b.H.

Attention: Mr. Stanley Ammons

September 18, 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 increase the monomer plus dimer specification to > 94% and submit a revised Lot Release Protocol.
2. Please submit the Polysorbate 80 stability testing results when available. As noted in your response to question 4 from the information request dated August 3, 2018, it should be available by the end of November 2018.
3. Regarding CC80988, please submit the updated document 056HBE714/01.
4. Please submit any stability data available for a lot, such as (b) (4) [REDACTED], which has a low level of Polysorbate 80 at time zero.

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 October 2, 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/DRPM

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Thank you