



Our Reference: BLA 125668/o

Octapharma Pharmazeutika Produktionsges.m.b.H.

Attention: Mr. Stanley Ammons

April 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:

In response to our IR of 2/23/2018 Question 1, you submitted the SAS programs as requested. However, you acknowledged that running programs requires a specific SAS set-up, so that the programs will not execute instantaneously when started in a different environment.

Please provide a simplified version of the program and a corresponding dataset that can be run without any special setting. Please avoid macros as much as possible.

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 May 11, 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