



Our Reference: BLA 125668/o

Octapharma Pharmazeutika Produktionsges.m.b.H.

Attention: Mr. Stanley Ammons

November 21, 2018

Sent by email

Dear Mr. Ammons:

We are reviewing your December 28, 2017, biologics license application (BLA), for Immune Globulin Subcutaneous (Human). We request that you make the following postmarketing commitment:

1. Octapharma commits to validating the following assays for CUTAQUIG's IgG Content (b) (4) . SOPs for the methods and the validation studies will be submitted as a PMC Submission – Final Study Report by April 1, 2019.
2. Octapharma commits to setting a final (b) (4) specification following a year of release testing for CUTAQUIG. The final (b) (4) specification and justification will be submitted as a Prior Approval Supplement by January 1, 2020.

The review of this submission is on-going and issues may be added, expanded upon, or modified.

Please submit your response to this request as an amendment to this file by November 28, 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