



Our Reference: BLA 125668/o

Octapharma Pharmazeutika Produktionsges.m.b.H.

Attention: Mr. Stanley Ammons

August 3, 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. Since the manufacturing process is shared with Octagam, please list all manufacturing changes since production of the Cutaquig conformance lots. Please include all STNs and whether the submission has been approved or is still under review.
2. Please note Polysorbate 80 can undergo oxidation and aggregation under stressed conditions which has the potential to affect product stability. Please set a maximum mixing time for Step (b) (4) in the batch records. The time can be based on the mixing times for the conformance lots.
3. Since the percent of fragments and aggregates can more than meet the (b) (4) specification for each, please set the specification for 3% for each one.
4. Since Polysorbate 80 can be an important (b) (4) , please include Polysorbate 80 testing as part of stability studies for Cutaquig.

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 August 16, 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

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Thank you