



Our Reference: BLA 125668/0

Octapharma Pharmazeutika Produktionsges.m.b.H.

Attention: Mr. Stanley Ammons

September 25, 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. For the filter usage at Step (b) (4) ,
 - a. Are using (b) (4) approved for manufacturing US licensed Octagam 5% and 10% at the OPG facility? If yes, what is the associated submission tracking number (STN)?
 - b. Please provide the SOP or work aid which has detail descriptions on the condition when the (b) (4) can be used.
 - c. Please remove (b) (4) as it was not validated for manufacturing CUTAQUIG.
2. For the filter usage at Step (b) (4) ,
 - a. Please indicate the number of filters used during PPQ runs.
 - b. Only (b) (4) is allowed for Step (b) (4) . In Table 3 (eCTD Description of Process and Process Controls – add info), please change “yes” to “no” for Step (b) (4) under the column “Are they changed out during the batch? (yes/no)”.
3. For the filter usage at Step (b) (4) – Formulation and (b) (4) Filtration,
 - a. Preparation of (b) (4) is not included in your master batch record. Please explain.
 - b. Please remove (b) (4) as it was not validated for manufacturing 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 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

THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW

If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by telephone and return it to us at the above address by mail.

Thank you