



Our Reference: BLA 125668/o

Octapharma Pharmazeutika Produktionsges.m.b.H.

Attention: Mr. Stanley Ammons

July 19, 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:

Determination of (b) (4) Activity using the (b) (4) method validation

1. In the document, 138VAL321 FC 81x/01, you have reported the range of the Determination of (b) (4) Activity using (b) (4) method as (b) (4). However, you provided results of (b) (4) drug product, which shows the Limit of Quantitation (LOQ) of the method is (b) (4). That is, (b) (4) (LOQ) is the lowest point of the assay range. Please revise your document to indicate the range of the assay as (b) (4).
2. In the Specificity study, you presented results to show that (b) (4) spiked in (b) (4) generates a “small reaction” and indicated that (b) (4) preparation contains traces of (b) (4) or other activated substances which react in (b) (4) deficient plasma. Please provide data from the assay of (b) (4) using the Determination of (b) (4) Activity using (b) (4) method to show that (b) (4) contains measurable (b) (4) activity.

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 July 31, 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