

From: Levi, Mark
Sent: Thursday, 19 July, 2018 15.09
To: 'barbara.rangetiner@octapharma.com'; Gorsche, Rita; 'Wittig, Anja'
Cc: 'Ammons, Stanley'
Subject: FDA IR for BLA 125587

Sensitivity: Confidential

Our Reference: BL 125587/0

Dear Dr. Rangetiner:

We are reviewing your resubmitted biologics license application for Immune Globulin Intravenous (Human) 10. We determined that the following information is necessary to continue our review:

1. Given that no small scale studies have been performed and no other supporting data were provided, the requested (b) (4) life cycles for (b) (4) are not acceptable. Based on the life cycle study reports (b) (4) (750RQP007_01) and (b) (4) (750RQP008_01) submitted in Amendment 61 on July 18, 2018, the (b) (4) are only allowed to use up to (b) (4) cycles with maximum hold times of (b) (4), respectively. Please update your material batch record and other affected documents accordingly.

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

Please submit your response to this information request as an amendment to this file by July 20, 2018, referencing the date of this request. If you anticipate you will not be able to respond by this date, please contact me 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.

Please confirm receipt of this email.

The action due date for this file is Aug. 2, 2018.

Regards, Mark Levi
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