

From: Levi, Mark
Sent: Friday, 13 July, 2018 11.04
To: 'barbara.rangetiner@octapharma.com'; 'Renner, Iris'
Cc: 'Ammons, Stanley'
Subject: FDA IR for BLA 125587 Fri 2

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. Please remove “(b) (4) plasma” under “Proportion” in Lot Release Protocol.
2. Please provide life cycle study updates for (b) (4). Please note that the life cycles of (b) (4) usage are based on your validation studies (750RQP007_00_ (b) (4) and 750RQP008_00_ (b) (4), submitted in response to the June 08, 2018 IR). Given that no small scale studies have been performed and no other supporting data were provided, the (b) (4) are allowed to use up to (b) (4) cycles, respectively.

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 18, 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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