

From: Wittig, Anja <anja.wittig@octapharma.com>
Sent: Friday, 08 June, 2018 02:18
To: Levi, Mark
Cc: Ammons, Stanley; Rangetiner, Barbara
Subject: RE: FDA IR for BLA 125587

Sensitivity: Confidential

Dear Mark,

We herewith confirm receipt of this email.

Kind Regards,
Anja

Anja Wittig
Manager
International Regulatory Affairs Department

Octapharma Pharmazeutika Prod.ges.m.b.H. | Oberlaaer Strasse 235 | A-1100 Vienna Austria |
Office: +43 (0) 1 610 32 1707 | Fax: +43 (0) 1 610 32 9122 | anja.wittig@octapharma.com
| www.octapharma.com

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From: Levi, Mark [mailto:Mark.Levi@fda.hhs.gov]
Sent: Thursday, June 07, 2018 11:51 AM
To: Rangetiner, Barbara <barbara.rangetiner@octapharma.com>
Cc: Ammons, Stanley <stanley.ammons@octapharma.com>
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. Please include the following information into the eCTD section 3.2.S.2.2 Description of Manufacturing Process and Process Controls:
 - a. A table containing Panzyga manufacturing process control parameters and acceptance limits.
 - b. Process segments and time limits (ranges) (your response to Question 2 of FDA Information Request dated May 01, 2018).

- c. The table you provided in response to Question 12 of FDA Information Request dated May 01, 2018.
- d. How the batch numbers are named throughout Panzyga's manufacturing process (your response to Question 10 of FDA Information Request dated April 02, 2018).
2. Based on the filter usage information provided in your response to Question 12 of FDA Information Request dated May 01, 2018, please update your master batch record accordingly. Please remove any language about (b) (4)
3. You asked for (b) (4) cycle lifetime for (b) (4). Please provide small scale studies to support your requests. If already submitted, please indicate their locations in eCTD.
4. Please update your final container drug product specifications according to your response to Question 7 of FDA Information Request dated May 01, 2018.
5. Please insert a footnote in Table 45 of report 150PPQR1726/00, explaining the reference standard unit difference for (b) (4) measured by (b) (4) assay and (b) (4) activity measured by (b) (4) assay.
6. Please define an in-process acceptance criterion for "(b) (4)"
7. Please provide an update on the column life-cycle studies for (b) (4)

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 June 17, 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

Mark Levi, PhD

Regulatory Project Management Staff

Center for Biologics Evaluation and Research

Office of Tissues and Advanced Therapies

U.S. Food and Drug Administration

Tel: +1 (240) 402-9662 Mobile +1 (301) 908-5787

mark.levi@fda.hhs.gov

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