

From: Wittig, Anja <anja.wittig@octapharma.com>  
Sent: Tuesday, 03 April, 2018 05:52  
To: Levi, Mark  
Cc: Rangetiner, Barbara  
Subject: RE: FDA IR for BLA 125587

Sensitivity: Confidential

Dear Mark,

I confirm receipt of your email.

Kind regards,  
Anja

From: Rangetiner, Barbara  
Sent: Dienstag, 03. April 2018 06:34  
To: Gorsche, Rita; Wittig, Anja  
Subject: Fwd: FDA IR for BLA 125587  
Sensitivity: Confidential

Anfang der weitergeleiteten Nachricht:  
Von: "Levi, Mark" <Mark.Levi@fda.hhs.gov>  
Datum: 2. April 2018 um 21:58:54 MESZ  
An: "barbara.rangetiner@octapharma.com" <barbara.rangetiner@octapharma.com>  
Kopie: "stanley.ammons@octapharma.com" <stanley.ammons@octapharma.com>  
Betreff: FDA IR for BLA 125587  
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. For CC55648,
  - a. Why the maximum batch size in (b) (4) needs to be (b) (4) when the Fractionation area was extended (CC39087, CC39251, CC43151)?
  - b. Was the maximum size of (b) (4) validated? Please submit the validation report.
  - c. Was there any Panzyga lot manufactured with maximum batch size of (b) (4)?
2. For corporate CC 35306, local CC 51090, how the (b) (4) from the new supplier (b) (4) is qualified? What is the (b) (4)? How the (b) (4) expiration date is determined?

3. Please provide detailed information and rational for the change CC59326 at Step (b) (4).

4. For CC47394 and CC56874,

a. Why the new tank (b) (4) was added in addition to (b) (4) ?

b. Is the configuration of (b) (4) the same as (b) (4) ?

c. How the (b) (4) were validated for the (b) (4) ?

d. How the mixing of (b) (4) is compared with (b) (4) ?

5. Process Performance Qualification Report 150PPQR1726/00,

(b) (4)

6. Nanofiltration

(b) (4)

7. (b) (4) interim report 750RQP007.00,

(b) (4)

8. (b) (4) interim report 750RQP008.00,

(b) (4)

9. In the first paragraph of section 2.2, it states that “the monomer and dimer content is ? 90%”. This is inconsistent with your current drug production specification for monomer and dimer content (b) (4). Please correct it.

10. Please provide information on how the batch numbers are named throughout Panzyga’s manufacturing process. If already provided, please indicate its location in eCTD.

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 April 12, 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 Sept. 28, 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  
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