

From: Wittig, Anja <anja.wittig@octapharma.com>  
Sent: Thursday, 05 July, 2018 08.35  
To: Levi, Mark  
Cc: Ammons, Stanley; Rangetiner, Barbara  
Subject: RE: FDA IR for BLA 125587

Sensitivity: Confidential

Dear Mr. Levi,  
We herewith confirm receipt of this email.  
Kind Regards,  
Rita Gorsche

On behalf of  
Anja Wittig  
Manager  
International Regulatory Affairs Department

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From: Rangetiner, Barbara  
Sent: Mittwoch, 04. Juli 2018 15:35  
To: Gorsche, Rita  
Subject: FW: FDA IR for BLA 125587  
Sensitivity: Confidential

From: Levi, Mark [mailto:Mark.Levi@fda.hhs.gov]  
Sent: Mittwoch, 04. Juli 2018 15:10  
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:

Regarding the response to Question 5 from the May 1, 2018 IR, please provide the list of actual mixing speeds used at each step for the manufacture of the conformance lots.

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 9, 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  
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