

From: Levi, Mark  
Sent: Friday, 27 July, 2018 06.23  
To: 'barbara.rangetiner@octapharma.com'; 'Gorsche, Rita'  
Cc: Ammons, Stanley  
Subject: FDA IR for BLA 125587

Sensitivity: Confidential

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 your response to the July 13 Information Request, please note that your mixing studies did not include product impact data (e.g., aggregates, etc.) for the maximum mixing speeds; therefore, please set the maximum mixing speed for those steps according to the maximum mixing speeds used in the Process Validation.

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 30, 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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Center for Biologics Evaluation and Research  
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