

From: Wittig, Anja <anja.wittig@octapharma.com>
Sent: Thursday, 21 June, 2018 06.19
To: Levi, Mark
Cc: Rangetiner, Barbara
Subject: RE: FDA IR for BLA 125587

Sensitivity: Confidential

Thank you!
Kind Regards,
Anja

From: Levi, Mark [mailto:Mark.Levi@fda.hhs.gov]
Sent: Donnerstag, 21. Juni 2018 12:14
To: Wittig, Anja
Subject: RE: FDA IR for BLA 125587
Sensitivity: Confidential

That will be ok.

Cheers, Mark

Sent from my iPhone on Verizon.

From: Wittig, Anja <anja.wittig@octapharma.com>
Date: June 21, 2018 at 04:09:14 EDT
To: Levi, Mark <Mark.Levi@fda.hhs.gov>
Cc: Rangetiner, Barbara <barbara.rangetiner@octapharma.com>
Subject: RE: FDA IR for BLA 125587

Dear Mark,

This is to confirm that we have received your email.

We are currently preparing our response this Information Request dated June 20, 2018.

Response due date is June 24, 2018. Since this is a Sunday we would like to submit our response on Monday morning (Vienna time), June 25, 2018, i.e. FDA will receive our responses on Monday before start of work.

Please let us know if this is acceptable for you.

Kindest Regards,
Anja

Anja Wittig
Manager
International Regulatory Affairs Department

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From: Rangetiner, Barbara
Sent: Mittwoch, 20. Juni 2018 14:12
To: Wittig, Anja
Subject: FW: FDA IR for BLA 125587
Sensitivity: Confidential

From: Levi, Mark [mailto:Mark.Levi@fda.hhs.gov]
Sent: Mittwoch, 20. Juni 2018 13:49
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:

Please provide a copy of English summary of the deviation reports for the following deviations: 48900, 58464, 59272, 59818, 60829, 64700, 65035, 65318, 66208, 66304, 66624, 68487, 69766, 69975, 70177, 70333, 72961, 74612, 76966, 76967, 78104, 78554, 79076, 81392, 81935, 81975, 82369, 82370, 82386, 82635, 82961, 85436, 74334, 75270.

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 24, 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
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mark.levi@fda.hhs.gov

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