

From: Wittig, Anja <anja.wittig@octapharma.com>
Sent: Thursday, 08 March, 2018 05:07
To: Levi, Mark
Cc: Rangetiner, Barbara
Subject: RE: FDA IR for BLA 125587/0

Sensitivity: Confidential

Dear Mark,

I confirm receipt of your email.

Kind regards,
Anja

From: Rangetiner, Barbara
Sent: Donnerstag, 08. März 2018 05:35
To: Gorsche, Rita; Wittig, Anja
Subject: Fwd: FDA IR for BLA 125587/0
Sensitivity: Confidential

Anfang der weitergeleiteten Nachricht:
Von: "Levi, Mark" <Mark.Levi@fda.hhs.gov>
Datum: 8. März 2018 um 02:14:37 MEZ
An: "'barbara.rangetiner@octapharma.com'" <barbara.rangetiner@octapharma.com>
Kopie: "stanley.ammons@octapharma.com" <stanley.ammons@octapharma.com>
Betreff: FDA IR for BLA 125587/0
Dear Barbara,

We are reviewing the Resubmitted BLA and have the following request for information:

Please submit an updated list of changes related to the Panzyga process since the issuance of the CR Letter.

Please confirm receipt of this email and replay with an Amendment to the submission by 19 March 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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mark.levi@fda.hhs.gov

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