

From: Levi, Mark  
Sent: Friday, 13 July, 2018 13.28  
To: 'barbara.rangetiner@octapharma.com'; 'Renner, Iris'  
Cc: 'Ammons, Stanley'  
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:

On Page 2 of the LRP template

1. For (b) (4), please state the results of the test and not "passed test"

They need to state the results and NOT Passed test on the LRP template.

Please make the correction and send an updated LRP as an Amd to BLA 125587.

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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