

From: Levi, Mark
Sent: Wednesday, 11 July, 2018 10.01
To: 'barbara.rangetiner@octapharma.com'
Cc: 'Renner, Iris'; 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:

Please correct the following items in the lot release protocol template updated on 01/31/2018 in amendment 125587/0.45:

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1. For Processing method: Please add (b) (4)
2. For the Location, Filling will only be done at Vienna at this time, so please remove Lingolsheim.

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3. For (b) (4), please state the results of the test and not "passed test"
4. For IgA content, the specifications should be ? (b) (4) (refer to Specs received in 125587/0.51)
5. (b) (4) specifications should be ? (b) (4) (refer to Specs received in 125587/0.51)
6. Sodium specifications should be ? (b) (4) (refer to Specs received in 125587/0.51)
7. (b) (4) specifications should be ? (b) (4) (refer to Specs received in 125587/0.51)

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8. For Fragments in (b) (4), please include the specification at end of shelf life (? 3 % (b) (4))

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 (updated Lot Release Protocol template) as an amendment to this file by July 13, 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

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