

From: Hooban, Christopher
Sent: Friday, June 05, 2015 8:26 AM
To: Ammons, Stanley
Cc: Cagungun, Nannette
Subject: Information Request - BL 125587/0; Original BLA; Octapharma; ADD 14-APR-2016

Our Reference: BL 125587/0

Octapharma Pharmazeutika Produktionsges.m.b.H.

Dear Mr. Ammons:

We are reviewing your April 15, 2015 biologics license application (BLA) for Immune Globulin Intravenous, Human 10%. We determined that the following information is necessary to continue our review:

1. We request that the "Report of the Method Validation for the (b) (4) in Human Immunoglobulin by (b) (4)" located in folder 3.2.P.5.3 (Validation of Analytical Procedures) within GlobalSubmit be re-submitted with verification that pages 82-91 of the report can be accessed. The current document has an error on these pages which provides the following notice when accessed by reviewers: "An error exists on this page. Acrobat may not display the page correctly. Please contact the person who created the PDF documents to correct the problem."

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 10, 2015 referencing the date of this request. If you anticipate you will not be able to respond by this date, please contact the Agency immediately so a new response date can be identified.

The action due date for this file is April 14, 2016.

If you have any questions, please contact me at (240) 402-8376 or christopher.hooban@fda.hhs.gov.

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