

From: Hooban, Christopher
Sent: Wednesday, October 07, 2015 2:31 PM
To: Ammons, Stanley
Cc: Cagungun, Nannette
Subject: Information Request B (October 7, 2015) - BLA 125587/0

Our Reference: BL 125587/0
Original BLA

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 are providing the following comments and request for additional information to continue our review:

1. Please provide the measured trough level of measles' titers for all investigated patients, using a minimum protective level cut-off of 240 mIU/ml. Please provide the analysis of the data including modeling by proportional shrinking of results to simulate trough titers in each patient as if the product administered had an anti-measles antibody titer of 0.29 X CBER standard.

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 October 14, 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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