

From: Hooban, Christopher
Sent: Friday, May 29, 2015 2:05 PM
To: stanley.ammons@octapharma.com
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. In the final study report for NGAM-01, Table 14.3.1.1.3 indicates a reported total of 476 TEAEs in the safety population. Table 14.3.1.5 indicates a reported total of 477 TEAEs in the safety population. Which one is correct and why is there a discrepancy?

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 5, 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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