

From: Hooban, Christopher  
Sent: Wednesday, September 30, 2015 2:46 PM  
To: Ammons, Stanley  
Cc: Cagungun, Nannette  
Subject: Information Request (30 SEP 15) - STN 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 report your PK parameters of IgG and IgG subclasses based on age (0-<6, 6-<12, >12-<16, and >16 years of age). The PK parameters should be calculated based on baseline corrected and uncorrected concentrations of IgG and IgG subclasses. Please also report number of subjects in each age group, body weight, exact age, and baseline corrected and uncorrected PK parameters (arithmetic mean and standard deviation) in a tabulated form.
2. Please provide mean concentration-time plots (baseline corrected and uncorrected) for IgG and IgG subclasses for all age groups.

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 21, 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](mailto:christopher.hooban@fda.hhs.gov).

Chris Hooban, MS, MPH  
Regulatory Project Manager  
OBRR/CBER/FDA  
U.S. Food & Drug Administration  
White Oak Building 71, Room 4257  
Office: (240)402-8376  
Mobile: (240)762-2266  
Email: [christopher.hooban@fda.hhs.gov](mailto:christopher.hooban@fda.hhs.gov)

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