

From: Hooban, Christopher
Sent: Wednesday, October 21, 2015 2:22 PM
To: Ammons, Stanley
Cc: Cagungun, Nannette
Subject: Information Request (21 OCT 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 provide the information as described in the Table below. The PK parameter values (in the units as described in the Table) should be arithmetic mean and standard deviation.
 - a. A similar Table should be made for 4-weeks dosing.
 - b. Please describe your calculation for clearance and Vss.

3-weeks (baseline corrected)
3-weeks (baseline uncorrected)

Age groups

0<6

years

6-<12

years

12-<16

years

16-75

years

0<6

years

6-<12

years

12-<16

years

16-75

years

N

Cmax

(mg/mL)

AUC (0-
tau)
(mg*hr/mL)

CL (mL/hr
per kg)

V_{ss}
(mL/kg)

Half-life
(hrs)

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 28, 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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