

From: Hooban, Christopher
Sent: Thursday, July 16, 2015 7:01 AM
To: Ammons, Stanley
Cc: Cagungun, Nannette
Subject: (b) (4) Assay 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 are providing the following comments and request for additional information to continue our review:

1. Please make following corrections in your SOP (130SOP071/04) and validation report (000VAL071 FC 8xx IP 7xx/02) for LOQ and range of (b) (4) percentage determination using (b) (4) and resubmit for review:

a. Range is established by confirming that the analytical procedure provides an acceptable degree of linearity, accuracy and precision. According to provided results, range for (b) (4) percentage should be (b) (4) instead of (b) (4).

b. LOQ is the lowest amount of analyte in a sample which can be quantitatively determined with acceptable accuracy and precision. According to provided results, LOQ for (b) (4) percentage should be (b) (4) instead of (b) (4).

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 July 30, 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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