

From: Hooban, Christopher
Sent: Friday, October 30, 2015 11:13 AM
To: Ammons, Stanley
Cc: Krammer, Marlene; Cagungun, Nannette
Subject: Information Request (October 30, 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 modify your method of identity testing for Newgam so that can specifically differentiate between Octagam, Newgam, and any other products in your facilities. Please submit the new testing methods and their validations.
2. Please increase your anti-measles antibody titer specification to (b) (4) CBER Lot 176 (b) (4) for a 10% solution).
3. Please withdraw from your BLA submission any manufacturing option involving the use of (b) (4) during your nanofiltration step.

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 November 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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