

From: Cagungun, Nannette
Sent: Friday, October 23, 2015 12:32 PM
To: Ammons, Stanley (stanley.ammons@octapharma.com)
Cc: Hooban, Christopher; Krammer, Marlene
(marlene.krammer@octapharma.com)
Subject: IGIV (H), 10%, nformation Request

Our Reference: BL 125587/0

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 request for additional information:

1. With regard to the the (b) (4) assay, we noticed that the samples used in your validation report (000VAL071 FC 84x 85x IP 7XX/03) for this method are Octagam final products. Only the specificity was re-evaluated in the supplement report (000VAL071 FC 84x 85x IP 7xx/01 supplement 1) with Newgam samples. Please explain why the Newgam samples have equivalent outcome for validation characteristics of linearity, range, accuracy, precision, LOQ and robustness as Octagam samples.

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 6, 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 Christopher Hooban at (240) 402-8376 or christopher.hooban@fda.hhs.gov.

Sincerely,

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