

From: Hooban, Christopher
Sent: Thursday, September 24, 2015 12:46 PM
To: Ammons, Stanley
Cc: Cagungun, Nannette
Subject: Information Request (24 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 provide an update on your ongoing stability studies, along with the raw data in an excel spreadsheet. If the 24 months time-point data for all conformance lots are not available yet (Study 13P003), please indicate when the data can be provided for agency review.

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 8, 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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