

From: Hooban, Christopher
Sent: Monday, July 27, 2015 9:15 AM
To: 'Ammons, Stanley'
Cc: Cagungun, Nannette
Subject: Information Request

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 stability study reports, along with the stability data in an excel spreadsheet, for the following materials or products:
 - a) (b) (4) for clinical, conformance, and consistent lots
 - b) (b) (4) for clinical and conformance lots
 - c) Final product for clinical lots
2. Please provide an excel spreadsheet for the stability data provided in study 13P003, 14P022 and 14P020.
3. In the stability study 14P022, it stated (page 5) that "...during the first three month the product may be stored at temperatures above +8°C (46°F) and below +25°C (77°F) After the first three month the product may be stored at temperatures above +8°C (46°F) and below +25°C (77°F) for up to further 6 months ...", i.e., totally up to 9 months of storage above +8°C (46°F) and below +25°C (77°F) is proposed. However in the labelling text, it stated that "...within its shelf-life, the product may be stored at +25°C (77°F) for up to 6 months...", i.e. totally up to 6 months of storage above +8°C (46°F) and below +25°C (77°F) is proposed. Please clarify the apparent discrepancy of your proposed storage condition for the final product.

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 August 3, 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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