

From: Hooban, Christopher
Sent: Friday, May 29, 2015 10:14 AM
To: 'stanley.ammons@octapharma.com'
Cc: Cagungun, Nannette
Subject: *This email corrects a typo found in the IR sent on May 28 2015* Information Request - BL 125587/0; Original BLA; Octapharma; ADD 14-APR-2016

This email corrects a typo found in the information request sent on May 28, 2015.

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 determined that the following information is necessary to continue our review:

1. In reviewing your BLA submission (STN 125587), FDA has noted differences in terminology used to describe the condition under study. The Title Page and text of the NGAM-02 final study report indicate the condition under study as Primary Immune Thrombocytopenia (without referencing “chronic” or “adults”) whereas the BLA cover letter and Full Prescribing Information (FPI) refer to Chronic Thrombocytopenic Purpura in Adults. The NGAM-02 List of Abbreviations page is informative: “ITP = Immune thrombocytopenia (former = idiopathic thrombocytopenic purpura)”. FDA acknowledges that the two names are commonly used interchangeably among clinicians to refer to the same condition.

Please submit a revised cover letter clarifying the precise indication you seek and a brief explanation for the differences noted.

2. Please review the draft package insert (PI) to ensure it contains the precise indication you are seeking. Please resubmit with the needed modifications if the PI needs to be updated.

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 June 5, 2015 referencing the date of this request. Please include both a red-line strike out and clean copy of the revised package insert in WORD format. 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.

Chris Hooban
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OBRR/CBER/FDA

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