



Our Reference: BLA 125668/o

Octapharma Pharmazeutika Produktionsges.m.b.H.

Attention: Mr. Stanley Ammons

August 8, 2018

Sent by email

Dear Mr. Ammons:

We are reviewing your December 28, 2017, biologics license application (BLA), for Immune Globulin Subcutaneous (Human). We are providing the following comments and request for revisions is necessary to continue our review:

1. In section 5 *Warnings and Precautions* of the proposed package insert, you have mentioned the following three adverse events:
 - Renal Dysfunction/Failure in section 5.4 on page 12 (125668/o, Module 5.4)
 - Hemolysis in section 5.5 on page 13 (125668/o, Module 5.4)
 - TRALI in section 5.6 on page 13 (125668/o, Module 5.4)

However, you have not included these adverse events in the list of safety concerns in the Risk Management Plan (RMP).

2. Please revise the RMP to include the risks mentioned above: Renal Dysfunction/Failure (Identified risk), Hemolysis (Identified risk), and TRALI (Potential risk) in appropriate sections and please propose actions to address these risks.

The review of this submission is on-going and issues may be added, expanded upon, or modified.

Please submit your revised RMP as an amendment to this file by August 15, 2018, 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.

If we determine that your response to this information request constitutes a major amendment, we will notify you in writing.

The action due date for this file is December 29, 2018.

Please send an email message acknowledging receipt of this request.

If you have any questions, please contact me.

Sincerely,
Edward Thompson
Regulatory Project Manager
FDA/CBER/OBRR/RPMS

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Thank you