



Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Biologics Evaluation and Research

To: To File (BLA STN **125587/0**)

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Applicant: Octapharma Pharmazeutika Produktionsges. M.b.h.

Product: Immune Globulin Intravenous, Human 10% (Panzyga®)

Subject: Addendum to Final Review: original BLA – Stability Section

RECOMMENDATION

This BLA submission is recommended for approval.

EXECUTIVE SUMMARY

In the final review memo uploaded to EDR, the following item was recommended

The proposed shelf life for drug product can't be granted, instead the following storage condition and shelf life is recommended: Drug product can be stored at 5 ± 3 °C for up to 24 months. Within its shelf life, this product can't be stored at ≤ 25 °C. This condition should be applied to product transportation as well.

However, after discussion with supervisors and the available stability data was re-assessed and found to be acceptable, therefore this recommendation has been removed.

The proposed storage condition and comments were updated and shown below:


Materials	Proposed by Sponsor	Comments
(b) (4)	(b) (4)	Acceptable
(b) (4)	(b) (4)	Acceptable
Drug Substance (b) (4)	(b) (4)	Acceptable
Drug Product (Final Container)	5 ± 3 °C for up to 24 months; within its shelf life, the product was proposed to be stored at ≤ 25 °C for up to 6 months	Acceptable

CMC REVIEW SUMMARY

This addendum review only covers temperature excursion studies:

1. Temperature excursion studies performed covered (b) (4) or more months of temperature excursion at 25 °C during (b) (4) storage conditions:

(b) (4)




2. Results

The temperature excursion studies for both conformance and consistency batches are not available yet, but the studies for clinical lots have been complete.

a) Clinical lots- Study A

(b) (4)



The study was complete and no other issues were identified (Figures below).

b) Clinical lots – Study B

One deviation was noticed (deviation no. 7373): after (b) (4) month time point, the (b) (4) data for batch (b) (4) was above the internal release limit, measured with the (b) (4) method. (b) (4) for this time point passed when tested with (b) (4) method. At (b) (4) months, the (b) (4) was normal. The (b) (4) using (b) (4) method was tested for information only. In addition, the same batch was placed under temperature study A as well and no deviation was observed. This appears to be acceptable.

The study was complete and no other issues were identified (Data was not plotted).

