



ADDENDUM MEMORANDUM

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Office of Compliance and Biologics Quality (OCBQ)
Center for Biologics Evaluation and Research (CBER)
Food and Drug Administration (FDA)

To: Biologics License Application Submission Tracking Number # 125587/0

Subject: Review of Analytical Procedures for Drug Product of Biologics License
Application for PANZYGA® (NewGam 10%) Immune Globulin Intravenous,
Human 10%

Through: Lokesh Bhattacharyya, Ph.D., Lab Chief, LACBRP/DBSQC/OCBQ/CBER
William M. McCormick, Ph.D., Director, DBSQC/OCBQ/CBER

Applicant: Octapharma

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

Biologics License Application (BLA) Submission Tracking Number (STN) #: 125587

Submission received by CBER: April 15, 2015

Review completed: November 17, 2015

Executive Summary:

After comparing NewGam and Octagam ingredients and reviewing of the supplemental validation report of NewGam final product (FP) for (b) (4) determination, this reviewer concludes that the method is adequately validated for the intended use.

Background

In the DBQSC PDR memo (dated Nov. 2, 2015) for (b) (4) assay, it is indicated that the method is adequately validated for Octagam FP. However, the pending issue is whether validation with Octagam FP is applicable to NewGam FP.

Documents Reviewed

Amendment 27, received Nov. 04, 2015

- Response to information request dated Oct. 23, 2015

Review Narrative


The response from the sponsor was received on Nov. 4, 2015 regarding FDA's concern whether validation results obtained with Octagam FP can be applied to NewGam FP. The sponsor pointed out that both Octagam and NewGam FP solutions have the same (b) (4). The difference in the (b) (4) in the NewGam FP. The comparison of the DP of Octagam and NewGam ingredients is showed in Table 1.

Table 1. Comparison of chemical ingredients between Octagam and NewGam

	Octagam 10%	NewGam
pH	4.5-5.0	4.5-5.0
Osmolality	310-380 mosmol/kg	240-310 mosmol/kg
Total protein	(b) (4)	(b) (4)
(b) (4)	(b) (4)	(b) (4)
Sodium	< 30 mmol/L	(b) (4)
(b) (4)	(b) (4)	(b) (4)
(b) (4)	(b) (4)	(b) (4)
(b) (4)	Maltose (b) (4)	Glycine 15.0-19.5 mg/mL
TnBP	(b) (4)	(b) (4)
Octoxynol	(b) (4)	(b) (4)
(b) (4)	(b) (4)	(b) (4)

During the (b) (4) assay, (b) (4)

(b) (4)



Conclusion

The method is sufficiently described and validated for the intended use.