



## MEMORANDUM

**From:** Marie J. Anderson, MS, PhD  
Division of Biological Standards and Quality Control (DBSQC)  
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 125776

**Subject:** Lot Release Protocol (LRP) template for Prothrombin Complex Concentrate (Human) - Ians

**Through:** Varsha Garnepudi, Branch Chief QAB/DBSQC/CBER/FDA  
Maryna Eichelberger, PhD, Director DBSQC/OCBQ/CBER/FDA

**Cc:** Ze Peng, PhD, Chair, DH/OPPT/OTP/CBER/FDA  
Eden Chane, RPM, DRMRR1/ ORMRR/OTP/CBER/FDA

**Applicant:** Octapharma Pharmazeutika Produktionsges.m.b.H. (Octapharma)

**Product:** Prothrombin Complex Concentrate (Human) - Ians

**Trade Name:** Balfaxar

**Summary:** The LRP template for Prothrombin Complex Concentrate (Human) – Ians submitted in amendment 125776/0.38 on June 1, 2023 is acceptable for use.

## **1 General Information**

### **1.1 CMC Review Identifiers and Dates**

**1.1.1 Biologics License Application (BLA) Submission Tracking Number (STN):**  
125776

**1.1.2 Submission received by CBER:** July 28, 2022

**1.1.3 Review completed:** June 9, 2023

**1.1.4 Material Reviewed:** BLA 125776

**1.1.5 Related Master File, INDs and BLAs:** N/A

## **2 Review**

### **2.1 Documents Reviewed**

LRP template submitted in BLA 125776 on July 28, 2022.

Revised LRP template and response submitted in amendment 125776/0.33 on April 5, 2023.

Revised LRP template submitted in amendment 125776/0.38 on June 1, 2023.

### **2.2 Review**

Octapharma submitted an LRP template to BLA 125776 on July 28, 2022. This template was reviewed by OTP/OPPT/DH, OCBQ/DBSQC and OCBQ/DMPQ/PRB with comments. An IR was submitted to Octapharma on March 31, 2023 requesting minor revisions regarding the sterility and endotoxin templates.

Octapharma submitted a response and revised LRP template in amendment 125776/0.33 on April 5, 2023. This template was reviewed by OCBQ/DBSQC and OCBQ/DMPQ/PRB with no comments.

Due to specification changes a revised LRP template was submitted by Octapharma in amendment 125776/0.38 on June 1, 2023. This LRP template was reviewed by OTP/OPPT/DH and OCBQ/DBSQC with no comments.

### **3 Conclusions**

The LRP template for Prothrombin Complex Concentrate (Human) – Ians submitted in amendment 125776/0.38 on June 1, 2023 is acceptable for use. This template may be used for future lot release submissions.