



MEMORANDUM

Date: 21 April, 2017

From: Varsha Garnepudi
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 Numbers # 125612**

Subject: **Review of Lot Release Protocol Templates for Drug Substance and Drug Product of Biologics License Application for Fibryna® Fibrinogen (Human)**

Through: William M. McCormick, Ph.D., Director, DBSQC/OCBQ/CBER/FDA
James L Kenney, D.Sc., Acting Director, DBSQC/OCBQ/CBER/FDA

Cc: Maruna Thomas, RPM, DRPM/OTAT
Ze Peng, Ph.D., Chair, BLA Review Committee, DPPT/OTAT

Applicant: Octapharma Pharmazeutika Produktionsges.m.b.H.

Products: Fibryna® Fibrinogen (Human)

1 General Information

1.1 CMC Review Identifiers and Dates

1.1.1 **Biologics License Application (BLA) Submission Tracking Numbers (STN) #:**
125612/0

1.1.2 Submissions received by CBER: June 09, 2016

1.1.3 Review completed: February 02, 2017

1.1.4 Material Reviewed:

Draft Lot Release Protocol Template submitted in amendment 125612/0 on 09-June-2017

2 Review

2.1 Documents Reviewed

1. Draft Lot Release Protocol Templates submitted in amendment
 - a. 125612/0.29 on 01-Jan-2017
 - b. 125612/0.32 on 26-Jan- 2017

2.2 Review

The lot release protocol template for STN 125612/0.

The submission is an original BLA 125612/0 submitted by Octapharma to obtain licensure for Fibryna® Fibrinogen (Human).

The following Information Request was sent on 03rd January 2017 to continue our review.

1. On pages 2, and 3 of 4, remove Sterile from the sterility test specification, the specification should be No Growth.
2. On page 2 of 4, General Safety, please change the specification to complies with 21CFR 610.11.

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

A response to the 03rd January 2017 information request was received in an amendment 125612/0.29 and 125612/0.32, on 11th and 26th January 2017. Items 1 and 2 were addressed in the lot release protocol template submitted in an amendment 125612/0.32.

2.3 Conclusions

Final Lot release protocol template submitted, as listed in section 2 for STN 125612/0 in this review is acceptable for use.