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Food & Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

DBSQC/OCBQ ANALYTICAL METHOD REVIEW MEMO

To: Biologics License Application, STN 125833/0

From: Yen B. Phan, MLS(ASCP)^{CM}, LMIVTS/DBSQC/OCBQ

Through: Maryna Eichelberger, Ph.D.
Division Director, DBSQC/OCBQ

Sponsor: Grifols Therapeutics LLC (Grifols)

Subject: Suitability of lot-release test methods for FESILTY® [Fibrinogen (Human) (BT524)] (b) (4) drug product

Recommendation: Approval with Post Marketing Commitment (PMC)

Executive Summary:

Analytical methods used for lot release of FESILTY® [Fibrinogen (Human) (BT524)] were reviewed by Yen B. Phan, MLS(ASCP)^{CM}, (LMIVTS), Parmesh Dutt, Ph.D., (LBRP) and Kouassi Ayikoe; Ph.D., (LAC). Their review memoranda are attached to this cover letter. The validation of the residual moisture test method for the FESILTY® drug product was determined to be inadequate to demonstrate the method's suitability for release testing. A fully validated residual moisture method using (b) (4) , to be provided as a PMC, will be needed to complete the review and make a final determination regarding the adequacy of the method.

Conclusion: The analytical methods and their validations and/or qualifications reviewed for the FESILTY® (b) (4) drug product were found to be adequate for their intended use, except for the outstanding issue related to the residual moisture method using NIRS for the FESILTY® drug product. Grifols has provided a written commitment to address this issue as a PMC.