



Our STN: BL 125833/0

FILING NOTIFICATION

February 21, 2025

Grifols Therapeutics, LLC
Attention: Sharleen Xiong, PhD, RAC
Director, R&D Regulatory Strategy
79 TW Alexander Drive
4101 Research Commons
Durham, NC 27709

Dear Dr. Xiong:

Please refer to your Biologics License Application (BLA) received December 27, 2024, submitted under section 351(a) of the Public Health Service Act (PHS Act) for Fibrinogen (Human) (BT524).

We also refer to your amendments submitted and received February 4, 2025, February 6, 2025, February 11, 2025, and February 12, 2025.

We have completed our filing review and have determined that your application is sufficiently complete to permit a substantive review. Under 21 CFR 601.2(a), this application is considered filed today. The review classification for this application is **Standard**.

The review goal date is December 27, 2025.

This acknowledgment of filing does not mean that we have issued a license, nor does it represent any evaluation of the adequacy of the data submitted.

This application is also subject to the provisions of "the Program" under the Prescription Drug User Fee Act (PDUFA). Refer to <https://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserfee/ucm446608.htm>.

We are reviewing your application according to the processes described in the guidance for industry and review staff *Good Review Management Principles and Practices for New Drug Applications and Biologics License Applications* at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/good-review-management-principles-and-practices-new-drug-applications-and-biologics-license>. Therefore, we have established internal review timelines as described in the guidance, which includes the timeframes for FDA internal milestone meetings (e.g., filing, planning, mid-cycle, team and wrap-up meetings). We plan to hold our internal mid-cycle review meeting on June 9, 2025. Please be aware that the timelines

described in the guidance are flexible and subject to change based on workload and other potential review issues (e.g., submission of amendments). We will inform you of any necessary information requests or status updates following the milestone meetings or at other times, as needed, during the process. We will communicate any anticipated postmarketing requirements by November 1, 2025. If major deficiencies are not identified during the review, we plan to communicate proposed labeling and, if necessary, any postmarketing commitment requests by November 27, 2025.

We are not currently planning to hold an advisory committee meeting to discuss this application.

At this time, we have not identified any potential review issues. Our filing review is only a preliminary review, and deficiencies may be identified during substantive review of your application. Following a review of the application, we shall advise you in writing of any action we have taken and request additional information if needed.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We acknowledge you have addressed PREA for this application.

If you have any questions, please contact the Regulatory Project Manager, Candace Jarvis, at (240) 402-8315 or by email at Candace.Jarvis@fda.hhs.gov.

Sincerely,

Mara Miller, MA
Director
Division of Review Management and Regulatory Review 2
Office of Review Management and Regulatory Review
Office of Therapeutic Products
Center for Biologics Evaluation and Research