Our STN: BL 103196/6012

SUPPLEMENT APPROVAL
August 21, 2025

Grifols Therapeutics LLC
Attention: Kelly Smith
8368 US 70 Bus Hwy West
Clayton, NC 27520

Dear Kelly Smith:

We have approved your request received April 22, 2025, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Antithrombin III (Human) to revise Section 8.4 Pediatric Use in the Prescribing Information label for THROMBATE III® [antithrombin III (human)] to include the safety and effectiveness that have been established in pediatric patients. The use of THROMBATE III in pediatric patients with hereditary antithrombin (AT) deficiency is supported by extrapolation of data from two clinical trials in adult patients.

LABELING

We hereby approve the draft content of labeling including the Package Insert submitted under amendment # 5001 (SN0225) dated July 11, 2025.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the final content of labeling (21 CFR 601.14) in Structured Product Labeling (SPL) format via the FDA automated drug registration and listing system, (eLIST) as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the Package Insert submitted on July 11, 2025. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As* at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

All final labeling should be submitted as Product Correspondence to this BLA, STN BL 103196/0 at the time of use and include implementation information on Form FDA 356h.

ADVERTISING AND PROMOTIONAL LABELING

You may submit two draft copies of the proposed introductory advertising and promotional labeling with Form FDA 2253 to the Advertising and Promotional Labeling Branch at the following address:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave.
WO71–G112
Silver Spring, MD 20993-0002

You must submit copies of your final advertising and promotional labeling at the time of initial dissemination or publication, accompanied by Form FDA 2253 (21 CFR 601.12(f)(4)).

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence or substantial clinical experience to support such claims (21 CFR 202.1(e)(6)).

We will include information contained in the above-referenced supplement in your BLA file.

Sincerely,

Asha Das, MD
Acting Director
Division of Clinical Evaluation Hematology
Office of Clinical Evaluation
Office of Therapeutic Products
Center for Biologics Evaluation and Research