Our STN: BL 102475/5802

SUPPLEMENT APPROVAL
July 31, 2026

Grifols Biologicals LLC
Attention: Kelly Smith
Grifols Therapeutics LLC
8368 Clayton Blvd
Clayton, NC 27520

Dear Kelly Smith:

We have approved your request received January 30, 2026, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Antihemophilic Factor/von Willebrand Factor Complex (Human) [ALPHANATE] for labeling changes to update the package insert to comply with the Pregnancy and Lactation Labeling Rule (PLLR) and to remove discontinued kits containing diluent labeled at Grifols Biologicals LLC in (b) (4) .

LABELING

We hereby approve the draft content of labeling Package Insert submitted under amendment 5006, dated July 29, 2026.

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 29, 2026. 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 102475 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,

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