Our STN: BL 125046/2156

SUPPLEMENT APPROVAL
April 28, 2026

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

Dear Kelly Smith:

We have approved your request received October 28, 2025, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Immune Globulin Injection (Human) 10% Caprylate/Chromatography Purified to include revisions to the prescribing information label in Section 1 INDICATIONS AND USAGE, Section 2 DOSAGE AND ADMINISTRATION, Section 3 DOSAGE FORMS AND STRENGTHS, Section 4 CONTRAINDICATIONS, Section 5 WARNINGS AND PRECAUTIONS, Section 6 ADVERSE REACTIONS, Section 7 DRUG INTERACTIONS, Section 8 USE IN SPECIFIC POPULATIONS, Section 11 DESCRIPTION, Section 12 CLINICAL PHARMACOLOGY, Section 14 CLINICAL STUDIES, Section 15 REFERENCES, Section 16 HOW SUPPLIED/STORAGE AND HANDLING, and Section 17 PATIENT COUNSELING INFORMATION, associated with the approval letter issued on October 20, 2025 (STN BL 125046/2129) for the alternate closure system for 50 mL, 100 mL, 200 mL, and 400 mL fills of GAMUNEX-C in sterilized bags (GAMUNEX-C FlexBag), filled at contract manufacturer, (b) (4) .

LABELING

Under 21 CFR 201.57(c)(18), patient labeling must be referenced in section 17 PATIENT COUNSELING INFORMATION. Patient labeling must be available and may either be reprinted immediately following the full prescribing information of the package insert or accompany the prescription product labeling.

We hereby approve the draft content of labeling Package Insert submitted under amendment 5, dated April 27, 2026, and the draft carton and container labels submitted and dated October 28, 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 April 27, 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.

CARTON AND CONTAINER LABELS

Please electronically submit final printed carton and container labels identical to the carton and container labels submitted on October 28, 2025, according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-certain-human-pharmaceutical-product-applications.

All final labeling should be submitted as Product Correspondence to this BLA, STN BL 125046/0 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)).

For each pending supplemental application for this BLA that includes proposed revised labeling, please submit an amendment to update the proposed revised labeling with the changes approved today.

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

Sincerely,

Patroula Smpokou, MD
Director
Division of Clinical Evaluation General Medicine
Office of Clinical Evaluation
Office of Therapeutic Products
Center for Biologics Evaluation and Research