Our STN: BL 125683/265

SUPPLEMENT APPROVAL
July 18, 2024

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

Dear Kelly Smith:

We have approved your request received September 18, 2023, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Immune Globulin Subcutaneous (Human) to include: 1) biweekly dosing for Primary Humoral Immunodeficiency (PI) patients 2 years of age and older switching from either an intravenous immune globulin or subcutaneous immune globulin; 2) addition of loading and maintenance dosing for treatment-naïve PI patients 2 years of age and older; 3) an increase to the maximal subcutaneous infusion rate to 35 mL/hour/site for PI patients 10 years of age and older.

The review of this supplement was associated with the following National Clinical Trial (NCT) numbers: NCT02806986 and NCT04566692.

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 and Patient Information submitted under BL 125683/265 amendment # 16, dated July 17, 2024.

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 17, 2024. 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 125683 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.

PEDIATRIC REQUIREMENTS

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 in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for ages less than two years for all dosing regimen changes because necessary studies are impossible or highly impracticable. This is because the number of patients diagnosed with primary humoral immunodeficiency in this age group is so small.

We are waiving the pediatric study requirement for ages 2 to less than10 years for the increased maximum rate of 35 mL/hour/site because the product does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in this age group and is not likely to be used in a substantial number of pediatric patients in this group. This is because the increased rate would not substantially change the time of infusion in this age group based on weight-based dosing that results in smaller volumes administered to young children, and thus the increased rate does not represent a meaningful clinical benefit.

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

Sincerely,

‘Lola Fashoyin-Aje, MD, MPH
Acting Director
Division of Clinical Evaluation General Medicine
Office of Clinical Evaluation
Office of Therapeutic Products
Center for Biologics Evaluation and Research