DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

Our STN: BL 125046/1325

BLS APPROVAL/ PMR FULFILLED LETTER

Grifols Therapeutics Inc.
Attention: Ms. Joan Robertson
8368 US 70 Business Highway West
Clayton, NC 27520

December 4, 2015

Dear Ms. Robertson:

We have approved your request to supplement your biologics license application for Immune Globulin Injection (Human) 10% Caprylate/Chromatography Purified to include labeling revisions to the package insert for the subcutaneous route of administration in pediatric patients (ages 2 to 16 years) with primary humoral immunodeficiency.

Please provide your final content of labeling in Structured Product Labeling (SPL) format and include the carton and container labels. In addition, please submit three original paper copies for carton and container final printed labeling. All final labeling should be submitted as Product Correspondence to this BLA at the time of use (prior to marketing) and include implementation information on FDA Form 356h.

In addition, please submit the final content of labeling (21 CFR 601.14) in SPL format via the FDA automated drug registration and listing system, (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Information on submitting SPL files using eLIST may be found in the guidance for industry titled, "SPL Standard for Content of Labeling Technical Qs and As at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

You may submit two draft copies of the proposed introductory advertising and promotional labeling with an FDA Form 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 advertisement 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)).

Please submit an amendment to all pending supplemental applications for this BLA that include revised labeling incorporating a revised content of labeling that includes these changes.

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 requirements for patients two years of age and younger because necessary studies are impossible or highly impracticable. There are too few children in this age group with this condition to study.

This supplement addresses your deferred pediatric study required under 505B(a) of the Federal Food, Drug, and Cosmetic Act as stated in required study #1, as identified in the October 13, 2010 approval letter for STN BL 125046/619. This requirement is as follows:

1. Deferred pediatric study under PREA for the treatment of Primary Humoral Immunodeficiency in pediatric patients ages 2 to 16.

We note that you have fulfilled the pediatric study requirement for ages 2 to 16 years for this application.

We will include information contained in the above-referenced supplement in your biologics license application file.

Sincerely,

Paul D. Mintz, MD
Director
Division of Hematology Clinical Review
Office of Blood Research and Review
Center for Biologics Evaluation and Research