



Our STN: BL 125683/0

**PROPRIETARY NAME ACCEPTABLE**

November 16, 2018

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

Dear Ms. Robertson:

We have reviewed your August 29, 2018, submission to your Biologics License Application (BLA) for Immune Globulin Subcutaneous (Human), requesting a proprietary name review for (b) (4)

In consultation with the Center for Biologics Evaluation and Research's Advertising and Promotional Labeling Branch (CBER/APLB), we conclude that, under the Federal Food, Drug, and Cosmetic Act and applicable regulations, (b) (4) is Acceptable.

If you have any questions, please contact the Regulatory Project Manager, Candido Alicea at (240) 402-8310.

Sincerely,

Ramani V. Sista, Ph.D.  
Director  
Office of Tissues and Advanced Therapies  
Center for Biologics Evaluation and Research