



Our STN: BL 125683/0

PROPRIETARY NAME ACCEPTABLE

March 28, 2019

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

Dear Ms. Robertson:

Please refer to your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Immune Globulin Subcutaneous (Human), 20%.

Please also refer to your amendment submitted January 18, 2019, received January 18, 2019, requesting a proprietary name review for XEMBIFY.

In consultation with 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, XEMBIFY 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
Division of Regulatory Project Management
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research