



Our STN: BL 125683/0

PROPRIETARY NAME WITHDRAWAL

March 26, 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).

Please also refer to your amendment submitted February 7, 2019, received February 8, 2019, requesting withdrawal of the proposed proprietary name, (b) (4).

The withdrawal procedure is now considered complete. You may submit [a] new proprietary name(s) for our consideration. Any proposed proprietary name(s) should comply with the regulations regarding false, misleading, or fanciful names, and regarding phonetic or orthographic similarities to other medicinal products.

If you have any questions, please contact me at (240) 402-8310.

Sincerely,

Cándido Alicea, Ph.D.
Regulatory Project Manager
Regulatory Management Staff
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research