



Our STN: BL 125683/0

FDA ASSIGNED SUFFIX

June 17, 2019

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

Dear Ms. Robertson:

Please refer to your Biologics License Application (BLA) submitted and received on July 9, 2018, under section 351(a) of the Public Health Service Act (PHS Act) for Immune Globulin Subcutaneous (Human), 20%.

FDA provides the suffix, -klhw, for inclusion in your proper name. Thus, we find the proper name, immune globulin subcutaneous, human-klhw, conditionally acceptable for your proposed product. Should your section 351(a) BLA be approved during this review cycle, immune globulin subcutaneous, human-klhw, will be the proper name designated in the license and you should revise your proposed labels and labeling accordingly.

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

Sincerely,

Basil Golding, MD
Director
Division of Plasma Protein Therapeutics
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research