



Our STN: BL 125683/0

BLA FILING NOTIFICATION

September 7, 2018

Grifols Therapeutics LLC
Attention: Joan Robertson
Vice President, Regulatory Affairs
8368 US 70 BUS HWY West
Clayton, North Carolina 27520

Dear Ms. Robertson:

This letter is in regard to your Biologics License Application (BLA) received on July 9, 2018, under section 351(a) of the Public Health Service (PHS) Act for Immune Globulin Subcutaneous (Human), 20% Solution.

We also refer to your amendments dated July 20, 2018, August 9, 2018, August 20, 2018, August 21, 2018, August 23, 2018, and August 29, 2018.

We have completed our filing review and have determined that your application is sufficiently complete to permit a substantive review. Under 21 CFR 601.2(a), this application is considered filed today. The review classification for this application is **Standard**; the review action due date is July 9, 2019. This acknowledgment of filing does not mean that we have issued a license nor does it represent any evaluation of the adequacy of the data submitted.

This application is also subject to the provisions of “the Program” under the Prescription Drug User Fee Act (PDUFA) (refer to <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm272170.htm>)

We are reviewing your application according to the processes described in the guidance for review staff and industry: *Good Review Management Principles and Practices for PDUFA Products* <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM079748>. Therefore, we have established internal review timelines as described in the guidance, which includes the timeframes for FDA internal milestone meetings (e.g., filing, planning, mid-cycle, team and wrap-up meetings). We plan to hold our internal mid-cycle review meeting on December 23, 2018. Please be aware that the timelines described in the guidance are flexible and subject to change based on workload and other potential review issues (e.g., submission of amendments). We will inform you of any necessary information requests or status updates following the milestone meetings or at other times, as needed, during the process. If major deficiencies are not identified during the review, we plan to communicate proposed labeling and, if necessary, any postmarketing requirement/commitment requests by June 9, 2019.

At this time, we have not identified any potential review issues. Our filing review is only a preliminary review, and deficiencies may be identified during substantive review of your application. Following a review of the application, we shall advise you in writing of any action we have taken and request additional information if needed.

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(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We acknowledge you have addressed PREA requirements for this application.

If you have any questions, please contact the Regulatory Project Manager, Patrick Riggins, at (240) 402-8346.

Sincerely yours,

Ramani Sista, PhD
Director
Division of Regulatory Project Management
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research