



Our STN: BL 125743/0

**RESUBMISSION ACKNOWLEDGEMENT**

July 28, 2023

GC Biopharma Corp.  
Attention: (b) (4)

Dear (b) (4)

Please refer to your resubmission to your Biologics License Application (BLA) received July 14, 2023, for immune globulin intravenous (human)-stwk, 10% liquid.

The resubmission contains GC Biopharma Corp.'s response to our February 25, 2022 complete response letter including chemistry, manufacturing, and controls (CMC) information to include facility and equipment, Labeling, Pediatric Research Equity Act (PREA) information, clinical information, meeting documents, and administrative documents.

We consider this a complete, Class 2 response to our action letter. Therefore, the goal date is January 13, 2024.

If you have any questions, please contact the Regulatory Project Manager, Nancy Skeeter, at (240) 402-5427 or by email at [nancy.skeeter@fda.hhs.gov](mailto:nancy.skeeter@fda.hhs.gov).

Sincerely,

Ramani Sista, PhD  
Director  
Division of Review Management and Regulatory Review 1  
Office of Review Management and Regulatory Review  
Office of Therapeutic Products  
Center for Biologics Evaluation and Research