



Our STN: BL 125743/0

**COMPLETE RESPONSE
EXTENSION**
February 21, 2023

GC Biopharma Corp.

Attention: (b) (4)

Dear Ms. (b) (4)

Please refer to your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act (PHS Act) for Immune Globulin (Human) [ALYGLO].

We also refer to your amendment received February 10, 2023, containing a request for an extension to resubmit the application that addresses all deficiencies identified in our Complete Response letter dated February 25, 2022.

We grant your request for an extension to resubmit this application by February 25, 2024. We remind you that per 21 CFR 314.110(c), an applicant's failure to resubmit the application within the extended time period or to request an additional extension may be considered a request by the applicant to withdraw the application.

If you have any questions, please contact me at (240) 402-5427 or by email at Nancy.skeeter@fda.hhs.gov.

Sincerely,

Nancy Skeeter
Regulatory Project Manager
Division of Regulatory Project Management
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research