

May 07, 2025

Department of Commerce
Bureau of Industry and Security
Docket No. 250414-0065
XRIN 0694-XC120

Subject: Public Comment Submission by GC Biopharma on Sec. 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients.

Dear Department of Commerce :

This letter and the attached supporting documentation outlines the effect of imported Immunological products (Harmonized Tariff Schedule 3002.13.00, 3002.14.00, 3002.15.00).

GC Biopharma USA, Inc. is a New Jersey corporation with its corporate headquarters located in Teaneck, New Jersey. We serve as the distribution, operations, and commercial business entity for GC Biopharma, which has its manufacturing facility and headquarters based in Yongin, Gyeonggi-do, South Korea. GC Biopharma manufactures Alyglo, a 10% Intravenous Immunoglobulin product that is FDA-approved for the treatment of Primary Immunodeficiency, a rare disease. To preserve access for US patients with rare diseases, policies should avoid outcomes that disrupt life-saving therapies for this US patient population.

Alyglo, a 10% Intravenous Immunoglobulin (IVIG), is manufactured in Ochang, South Korea, by GC Biopharma using US-based plasma proteins. GC Biopharma owns plasma centers in the US where the plasma is sourced. The manufacturing process is complex and takes 7-12 months to complete. Given the length of the manufacturing process, the complex regulatory environment, and the approval process, new manufacturing plasma facilities in the US typically require a significant upfront investment that takes a minimum of 5 years or more to construct and secure FDA approval.

Policies that disrupt the importation of Intravenous Immunoglobulin would not only create a potential drug shortage within the US, but they also endanger Americans living with serious and rare conditions that are chronic diseases.

We respectfully submit our review of the demand, production capacity, and the role of the global supply chain in the intravenous immunoglobulin US marketplace. Diversification of the supply chain of IVIG is essential. Thank you for your time and consideration of this submission. Please feel free to reach out to me at Lbetts@GCBiopharmaUSA.com and the GC Biopharma executive team for further information and questions regarding the critical importation of these pharmaceutical products.

Respectfully submitted,



Lisa M. Betts
Chief Operating Officer
GC Biopharma USA, Inc.