PUBLIC

SAMSUNG
BIOLOGICS

May 6, 2025

By Electronic Submission

The Honorable Jeffrey L. Kessler
Under Secretary
Bureau of Industry & Security
U.S. Department of Commerce
1401 Constitution Avenue NW
Washington D.C. 20230

RE: *Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients*, BIS-2025-0022 - XRIN 0694-XC120

Dear Under Secretary Kessler,

Samsung Biologics appreciates the opportunity to respond to the Department of Commerce ("Commerce") and Bureau of Industry and Security's request for public comments on the Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients pursuant to Section 232 of the Trade Expansion Act of 1962, as amended.[1]

Samsung Biologics, a Samsung affiliate, is a fully integrated Contract Development and Manufacturing Organization ("CDMO")[2] headquartered in Songdo, Incheon, South Korea. Since its establishment in 2011, Samsung Biologics has served the global pharmaceutical market as a trusted, one-stop solution provider for large molecule biologics development and manufacturing. The company has built a strong track record with a number of U.S. clients, beginning with its first contract in the early 2010s, and now collaborates with approximately half of its clients based in the United States. The company remains committed to strengthening the U.S. biologics sector by enhancing patient access to biological therapeutics through Samsung Biologics America ("SBA"), our U.S. subsidiary. Samsung Biologics has established a San Francisco office to support our CDMO services and a New Jersey office to facilitate technological integration with our clients. Together, Samsung Biologics and SBA provide trusted, life-saving services to U.S. clients and industry partners.

Samsung Biologics submits these brief comments to explain why Commerce should not include biologic therapies in the scope of the instant investigation. Simply put, imports of biologics do not pose a threat to U.S. national security. Biologic supply chains are very low-risk and limited to high-technology companies that manufacture in the United States and allied

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[1] *Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients*, 90 Fed. Reg. 15951 (Apr. 16, 2025).

[2] A CDMO is a company that provides pharmaceutical and biotechnology firms with comprehensive, contract-based services for both the manufacturing of drugs, allowing these firms to outsource everything from early formulation and process development to large-scale commercial production without needing to build or operate their own facilities.

nations. In fact, the U.S. biologics industry is a global leader and substantial in size, as conservative estimates suggest that the total U.S. biologics production capacity represents approximately 30% or higher of total global capacity. In other words, the United States has the single largest biologics production capacity of any country by a wide margin.

Given the substantial manufacturing base that exists in the United States for biologics, we hope that Commerce will conclude that biologics need not be included within the scope of the instant Section 232 investigation and import-restrictive measures (e.g., tariffs) are not warranted.

Samsung Biologics is grateful for the opportunity to participate in this process and is readily available to engage in further dialogue with the U.S. Government, as necessary, to aid Commerce's investigation.

Sincerely,

James Choi
Executive Vice President
Samsung Biologics