

**Samsung Bioepis Co., Ltd.
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**Public Comments on the
Section 232 National Security Investigation of
Imports of Pharmaceuticals and Pharmaceutical Ingredients
Docket No. 250414-0065; XRIN 0694-XC120
BIS-2025-0022¹**

Samsung Bioepis appreciates the opportunity to respond to the Department of Commerce and Bureau of Industry and Security's request captioned above for public comments as part of the ongoing Section 232 National Security Investigation of Imports of Semiconductors and Semiconductor Manufacturing Equipment.

Samsung Bioepis Co., Ltd. ("***Samsung Bioepis***"), established in 2012, is a biopharma company dedicated to developing, manufacturing, and commercializing biopharmaceutical medicine, including biosimilar medicines. We are transforming the way biologic medicines are brought to patients. We are a global leader in biosimilar medicines providing affordable high-quality medicines to patients in immunology, oncology, ophthalmology and rare disease.

We collaborate with U.S. companies to manufacture and commercialize our medicinal products to ensure a stable supply of our biosimilars for patients in the U.S. Our U.S. partners employ approximately 17,000 people within the country, with an estimated payroll of over \$1.8 billion in 2024². Samsung Bioepis' presence in the U.S. has contributed to new job-creation, not to mention provided job security to officers and employees of our U.S. partners.

Biosimilars have led to increasing savings for the U.S. healthcare system. Over the past seven years, biosimilar savings in the U.S. have increased at a CAGR of approximately 99%, reaching \$12.4 billion in 2023. More importantly, the full untapped potential of biosimilar savings is expected to exceed \$180 billion in the U.S. over the next five years. For the past 5 years, Samsung Bioepis has contributed to approximately \$3.2 billion in drug cost savings to U.S. taxpayers and patients. More than 176,000 American patients have benefited from our medicines without sacrificing affordability. Specifically, more than 138,000 patients are benefitting from our RENFLEXIS (infliximab; biosimilar of Remicade) medicine and are able to manage their conditions while maintaining a normal lifestyle.

In addition, we are committed to sourcing raw materials from U.S. suppliers and its trusted allies like the U.K., Australia, and EU countries, ensuring a secure and resilient supply chain that supports U.S. national interests. We also recognize the value of local

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 Based on average market wages.

manufacturing and are actively planning to increase our production capabilities through stronger partnerships with contract manufacturing organizations (CMOs) in the U.S.

Samsung Bioepis here forth respectfully submits its comments to the Department of Commerce and Bureau of Industry and Security on the Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients. Samsung Bioepis appreciates the opportunity to participate in this process and is readily available to engage in further dialogue with the U.S. Government.

Business Confidential Information

The request for public comments seeks a substantial amount of detailed and extremely sensitive business confidential information, and Samsung Bioepis has endeavored to be responsive to BIS's request. Pursuant to 15 C.F.R. § 705.6(a)(2), Samsung Bioepis requests business confidential treatment of the information contained in the confidential portion of this submission. The business confidential treatment is requested because the information includes business trade secrets, production, supply, and other confidential information, the disclosure of which would cause competitive harm to Samsung Bioepis.

Samsung Bioepis therefore has marked the attached confidential comments as "Business Confidential". We hereby request that BIS accord confidential treatment to those comments and the information transmitted herewith under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552(b); 15 C.F.R. § 4.9, and pursuant to the restrictions of the Trade Secrets Act, 18 U.S.C. § 1905. Samsung Bioepis customarily and actually treats this information as private, and we submit this information on the express condition that BIS will maintain the confidentiality of our response. If BIS receives a request, whether from an employee of any other agency of the United States or any other person, to review these comments or Samsung Bioepis' accompanying submission, Samsung Bioepis requests notification at once, prior to any disclosure, so that it may address such potential disclosure and, if necessary, pursue alternative remedies.

Sincerely,

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