May 7, 2025

Bureau of Industry and Security
U.S. Department of Commerce
1401 Constitution Avenue NW
Washington, DC 20230

Re: Docket No. BIS-2025-0022: XRIN 0694-XC120 Pharmaceuticals 232 Notice

Dear Under Secretary Kessler,

SK pharmteco appreciates the opportunity to respond to the U.S. Department of Commerce (DOC) Bureau of Industry and Security's (BIS) Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients [Docket Number BIS-2025-0022] as it considers the effects on the national security of imports of pharmaceuticals and pharmaceutical ingredients.

SK pharmteco Background

SK pharmteco is a leading domestic manufacturer of active pharmaceutical ingredients (APIs) and cell and gene therapies (CGTs) and is a leading domestic and global contract development and manufacturing organization (CDMO) for APIs and CGTs. Drawing from its long-standing industry presence, SK pharmteco leverages its expertise, technology, and legacy of innovation to offer integrated service offerings that cover process and analytical method development, optimization, validation, analytical testing, and commercial production.

SK pharmteco is a subsidiary of SK Inc. and is part of South Korea's second-largest conglomerate, which has extensive investment, operations, and employment across the United States. SK pharmteco is proud to employ more than 900 American workers at our small molecule and CGT manufacturing plants, process R&D plant, and analytical services facilities in Rancho Cordova, California; King of Prussia, Pennsylvania; and La Porte, Texas.

Leading domestic CDMOs like SK pharmteco play a central role in bolstering resiliency for U.S. pharmaceutical supply chains, including for research and development, scaling American small molecule manufacturing, ensuring quality and compliance, and developing the necessary infrastructure for U.S. CGT innovations and manufacturing. Across SK pharmteco's operations in the United States, our team is working to build out new capabilities and capacities that support domestic pharmaceutical supply chain development.

Considerations for Potential Action

SK pharmteco supports the Trump Administration's goal of enhancing U.S. pharmaceutical manufacturing capacity and critical supply chains for pharmaceuticals and patient health. As DOC considers the national security effects of imports of pharmaceuticals and pharmaceutical ingredients, SK pharmteco encourages the Administration to carefully examine the effects that different potential actions would have in advancing the Administration's goal of revitalizing domestic production capacity and capabilities.

SK pharmteco also commends President Trump's May 5 Executive Order (EO), *Regulatory Relief to Promote Domestic Production of Critical Medicines*. The EO is an important step to help reduce bureaucratic obstacles to critical domestic pharmaceutical manufacturing and improve access to the medicines Americans need. The EO also highlights that building new manufacturing capacity for pharmaceuticals and critical inputs has taken as long as five to 10 years and steps need to be taken to accelerate creation of new manufacturing capacity.

Given currently there may be limited domestic capacity to produce upstream raw materials or ingredients or certain downstream products needed to build out a domestic supply chain, DOC should take a targeted and staged approach should it decide to impose any tariffs to fully take into account the wide-range of current domestic and allied country production capability. Such a targeted approach can help ensure that any such actions would support, rather than undermine, building additional domestic capabilities and capacity.

As DOC assesses potential tariff or trade actions through its investigation, SK pharmteco encourages DOC to consider (1) adopting gradual phase-in periods to allows sufficient time to adjust supply chains and procurements for needed inputs that are not currently available in the United States; (2) limit or exclude any tariffs imposed on items destined for U.S.-headquartered CDMO manufacturing sites; and (3) limit or exclude tariffs on imports of necessary inputs or products from trusted U.S. allies like South Korea and in Europe to allow domestic capacity and capabilities time to ramp up.

Following the conclusion of its Section 232 investigation, should DOC recommend any tariff or import restrictions policies, those actions will be most effective if implemented in tandem with incentives to boost domestic manufacturing for pharmaceuticals, pharmaceutical ingredients, and other critical inputs, including tax incentives and long-term government contracts. Such incentives would help offset tariff costs imposed on U.S.-based CDMOs that import key raw materials and intermediates that are not currently available in the United States.

These additional incentives and actions will also create demand for developing domestic raw material and ingredient capacity in the United States, which over time will build out the domestic pharmaceutical supply chain. Phasing in any tariff or trade actions in parallel with building up support for development of domestic capacity and capabilities will also help mitigate potential disruptions to the supply chain and help accelerate the build out of domestic and more reliable cross-border supply chains with trusted partners.

Without complementary supply-side incentives that support investment and enhancements of the domestic pharmaceutical value chain, potential tariffs on pharmaceutical ingredients currently needed for domestic production and on certain pharmaceuticals may unintentionally constrain or slow the effort to build out domestic capabilities. Any such disruptions could also pose risks to American patients, increase costs of needed drugs, and even reduce the competitiveness for domestic innovators that currently require certain inputs for U.S. manufacturing and R&D.

SK pharmteco fully supports the Trump Administration's goal to build up domestic pharmaceutical capacity, and urges DOC to design and target any actions to prevent or minimize any potential supply chain disruptions or retaliatory actions from other countries that may harm American manufacturing and patient access. Any potential actions pursuant to this investigation will be most effective if they support business stability and also enhance cooperation with key trading partners who also have capabilities and capacity to augment the U.S. supply chain, such as strengthening economic ties with allies like South Korea.

Additional policies that would help advance the Trump Administration's goal and address any national security concerns arising from imports of pharmaceutical include:

- Update Annex II of the Reciprocal Tariff Executive Order to include HTS exemptions for specialty raw materials and intermediates;
- Adopt an approach that supports reshoring domestic pharmaceutical manufacturing that also strengthens supply chains with trusted international partners in Europe and Asia;
- Increase the capacity utilization rate of domestic CDMOs by creating a permanent Strategic API Reserve and prioritizing domestic CDMOs as suppliers to such Reserve; and
- Assess potentially forming a U.S. public-private CDMO coalition to share best practices, coordinate supply chain strategies, and improve supply chain resiliency and patient access.

Conclusion

SK pharmteco greatly appreciates the Trump Administration's commitment to expanding U.S. pharmaceutical and pharmaceutical ingredient manufacturing and supply chain resiliency. Aligning any potential tariff actions with domestic investment and operations incentives, policy support, and regulatory efficiencies can best achieve the shared goal of building out domestic pharmaceutical capacity building across the United States and ensure that the United States continues as the world leader in pharmaceutical innovation and development. As a global and domestic leader in API and CGT R&D and manufacturing, SK pharmteco appreciates the opportunity to support the strengthening of the U.S. pharmaceutical ecosystem, and looks forward to working with DOC and the Administration to advance U.S. pharmaceutical production.

Sincerely,

Signed by:
Arvind Singh
8B4C3E86ED434E1...

Arvind Singh
Vice President of Global Supply Chain Management, SK pharmteco
arvind.singh@skpt.com