May 7, 2025

Mr. Stephen Astle
Director, Defense Industrial Base Division
Office of Strategic Industries and Economic Security
Bureau of Industry and Security
US Department of Commerce

Submitted Electronically

Re: XRIN 0694–XC120: Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients

Dear Director Astle,

Dompé farmaceutici is grateful for the opportunity to comment on the Department of Commerce's Section 232 national security investigation of pharmaceuticals. Dompé is a global leader in the treatment of Neurotrophic Keratitis (NK), a rare disease of the eye that can result in vision loss, or even loss of the eye itself, if left untreated. We are writing to respectfully request that pharmaceutical products designated by the U.S. Food and Drug Administration (FDA) as both Orphan Drug and Breakthrough Therapy be exempted from industry tariffs.

Rare Diseases affect 30 million Americans of which two-thirds are children. 95% of these diseases currently have no cure, and the remaining 5% often have only one approved therapy, with the alternative being surgery or other invasive medical treatments. Due to economic challenges associated with small patient populations, the FDA created the **Orphan Drug Designation** (Orphan Drug Act of 1983) to assist companies in the development of these important therapies. The FDA also grants **Breakthrough Therapy Designation** (FDASIA, 2012) to products that demonstrate significant improvement over existing treatments for serious or life-threatening diseases.

Numerous peer-reviewed studies have demonstrated that tariffs are often passed on to consumers through higher prices. In the pharmaceutical sector, this dynamic is particularly challenging, as government programs such as Medicare and Medicaid specifically discourage price increases and impose financial penalties when prices rise beyond defined thresholds. Additionally, many existing contractual agreements prohibit unilateral price increases. In this context, manufacturers are limited in their ability to adjust pricing in response to tariffs. As a result, tariffs would

negatively impact their capacity to invest in future innovation and threaten the stability of the rare disease treatment ecosystem.

In the interest of patients suffering from rare disease, we respectfully request that the administration consider an exemption from tariffs for products that exclusively treat Orphan Drug indications and have also been recognized as Breakthrough Therapies. Our preliminary analysis estimates fewer than 100 products, representing less than 3% of total US pharmaceutical revenues, are included in this category. Exempting these products will safeguard the wellbeing of American patients and ensure uninterrupted access to care.

Dompé appreciates the Department of Commerce's consideration and welcomes the opportunity to discuss this or any other issues related to the treatment of patients suffering from rare disease.

Sincerely,

Nathalie Dompé, Co-CEO Dompé farmaceutici